IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-001715

ELI LILLY AND COMPANY,

Plaintiff,

v.

HYDRAMED IV LLC,

Defendant.

COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN, AND DECEPTIVE TRADE PRACTICES

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant HydraMed IV, LLC ("Defendant") has designed its website and advertising materials to deceive patients into thinking Defendant offers a way to obtain Lilly's clinically studied medicines, when in reality Defendant offers no such thing.[1] Lilly therefore brings this action under federal and state law to protect patients from Defendant's dangerous, deceptive, and unlawful practices.

2. For nearly 150 years, Lilly has worked tirelessly to develop and deliver trusted and innovative medicines that meet critical and unmet patient needs. Lilly's proprietary MOUNJARO® and ZEPBOUND® are two such first-of-their-kind medicines, which are indicated for the serious conditions afflicting many tens of millions of Americans. To advance treatment of these chronic conditions, Lilly used its extensive experience with world-class medicines to develop the brand-new class of GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) dual-receptor agonists, which includes tirzepatide, the active ingredient in Lilly's MOUNJARO® and ZEPBOUND®. Lilly's MOUNJARO® and ZEPBOUND® are the only FDA-approved GLP-1/GIP medicines.

3. Before obtaining FDA approval, Lilly's new medicines underwent years-long clinical trials, which tested them for safety, quality, and effectiveness on thousands of patients. When approving these medicines, the FDA called Lilly's "novel" MOUNJARO® an "important

[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

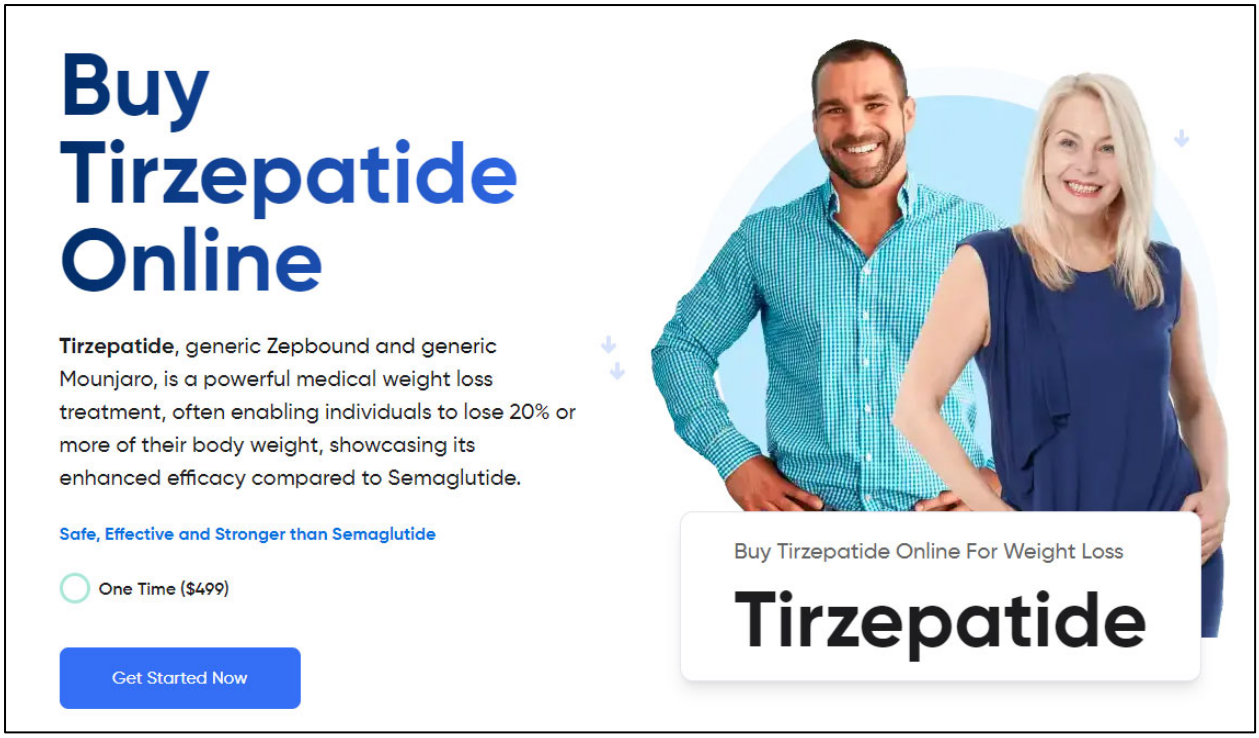
advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement); https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

4. Compounded products sold as "tirzepatide," meanwhile, are not approved or even reviewed by the FDA. Pharmacies currently offering compounded versions of tirzepatide are not required to follow the FDA's "good manufacturing practices," nor to comply with the same controls on sterility and safe storage as manufacturers of FDA-approved medicines. They are also not required to report adverse events—an important regulatory requirement imposed on manufacturers of FDA-approved medicines for patient safety. Compounded drugs are not tested for safety, quality, or efficacy in clinical trials. Accordingly, and as the FDA has warned, "compounded drugs pose a higher risk to patients than FDA-approved drugs," such as MOUNJARO® and ZEPBOUND®. https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages (FDA explainer on Drug Compounding).

5. Defendant falsely and unlawfully trades on Lilly's work, reputation, and goodwill, offering unproven and unapproved compounded drugs as if they were genuine Lilly medicines or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines, nor any FDA-approved "generic" version of them. Indeed, Defendant's drugs have undergone ***none*** of the rigorous studies or approval processes

that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO® and ZEPBOUND® is not merely deceptive—it's dangerous.

6. Defendant's intentional deception of patients starts from the top of its "Buy Tirzepatide Online" webpage, where it boldly and false defines "Tirzepatide" as "generic Zepbound and generic Mounjaro," as shown below:



7. Despite this impossible-to-miss headline, Defendant offers neither MOUNJARO® nor ZEPBOUND®, nor any "generic" version of them. In fact, there is ***no such thing*** as generic MOUNJARO® or generic ZEPBOUND®.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Colorado statutory and common law regarding deceptive trade practices. Lilly's claims arise out of Defendant's infringement of Lilly's rights in the

MOUNJARO® and ZEPBOUND® trademarks and Defendant's acts of false designation of origin, false advertising, and deceptive trade practices.

THE PARTIES

9. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

10. Defendant is a Colorado limited liability company with a principal place of business at 11990 Grant Street, Suite 550, Northglenn, Colorado 80233, in this District. Its sole member and registered agent is Bear Harper, with registered agent address 11990 Grant Street, Suite 550, Northglenn, Colorado 80233.

11. Defendant also conducts business at its website "https://hydramed.com." According to Defendant's website, Defendant offers services "throughout the greater Denver and Front Range areas." https://hydramed.com/areas-served/Colorado. Defendant additionally offers its services, including its "Tirzepatide" product "Shipped To You."

JURISDICTION AND VENUE

12. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates and conducts business in this District. Defendant is subject to personal jurisdiction in this District.

LILLY'S FDA-APPROVED TIRZEPATIDE MEDICINES: MOUNJARO® AND ZEPBOUND®

14. Lilly's MOUNJARO® is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, "Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement). MOUNJARO® targets this problem head-on using an innovative active pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly's MOUNJARO® was clinically proven to improve blood sugar control "more effective[ly] than the other diabetes therapies with which it was compared in clinical studies." *Id.*

15. The FDA approved MOUNJARO® and indicated it in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. As part of the approval process, Lilly submitted data on safety, quality, and effectiveness collected through clinical trials involving thousands of patients. Lilly's MOUNJARO® is thus proven safe and effective when used as directed.

16. In addition to MOUNJARO®, Lilly markets and sells ZEPBOUND®, another proprietary, FDA-approved treatment option containing the active pharmaceutical ingredient tirzepatide. With ZEPBOUND®, Lilly aims to help the many dozens of millions of American adults with obesity or with excess weight and weight-related medical problems lower their risks of cardiovascular disease and other leading causes of death. As the FDA has noted,

ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation. https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

17. As with MOUNJARO®, the safety, quality, and effectiveness of ZEPBOUND® was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND® and indicated it for adults with obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a BMI ≥ 27 kg/m2 or greater) and also have at least one weight-related additional condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight. It should be used with a reduced-calorie diet and increased physical activity.

18. Lilly's tirzepatide medicines are the result of billions of dollars of investments in research and development, which included dozens of studies and trials.

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp (FDA explainer on GMP). GMPs include "establishing strong quality management systems, obtaining appropriate quality raw materials,

establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories." *Id.* GMPs help "prevent instances of contamination, mix-ups, deviations, failures, and errors." *Id.*

20. Each step in Lilly's process to manufacture its tirzepatide medicines—from sourcing and chemical synthesis of the API to formulation and device assembly and packaging—requires extensive testing and controls and specialized equipment. Lilly's medicines must be, and always are, accompanied with important, FDA-approved labels, instructions, and warnings.

21. Lilly now promotes, offers, and sells MOUNJARO® and ZEPBOUND® medicines in Colorado and throughout the United States.

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

22. Lilly uses the trademarks MOUNJARO® and ZEPBOUND® (the "Lilly Marks") to identify and promote Lilly's proprietary, FDA-approved medicines with the active pharmaceutical ingredient tirzepatide. Lilly markets and sells MOUNJARO® and ZEPBOUND® throughout the United States using the Lilly Marks.

23. Lilly first adopted and used the MOUNJARO® mark at least as early as June 3, 2022, and has used the MOUNJARO® mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only diabetes medicine bearing the MOUNJARO® mark in many different channels, directed both to healthcare professionals and to patients.

24. Lilly is the owner of two federal trademark registrations for MOUNJARO®, U.S. Reg. Nos. 6,809,369 (issued August 2, 2022) and 7,068,463 (issued May 30, 2023). True and correct copies of Plaintiff Lilly's registrations for the MOUNJARO® mark are attached hereto as

part of **Exhibit A.** Lilly additionally has several pending applications to register its MOUNJARO® mark in connection with more classes, services, and goods, including U.S. Trademark Ser. Nos. 97/596,856, 97/668,206, and 98/253,743. As a result of its use of the MOUNJARO® mark, Lilly also owns valuable common law and other rights in and to the MOUNJARO® mark.

25. Lilly first adopted and used the ZEPBOUND® mark at least as early as November 30, 2023, and has used the ZEPBOUND® mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only weight-loss medicine bearing the ZEPBOUND® mark in many different channels, directed both to healthcare professionals and to patients.

26. Lilly is the owner of one federal trademark registration for ZEPBOUND®, U.S. Reg. No. 7,288,373 (issued January 23, 2024). A true and correct copy of Plaintiff Lilly's registration for the ZEPBOUND® mark is attached hereto as part of **Exhibit A.** Lilly additionally has several pending applications to register its ZEPBOUND® mark, including U.S. Trademark Ser. Nos. 97/530,451, 97/530,456, and 98/295,137. As a result of its use of the ZEPBOUND® mark, Lilly also owns valuable common law and other rights in and to the ZEPBOUND® mark.

27. Lilly conceived the Lilly Marks to stand out in the marketplace. The Lilly Marks do not describe any attributes of either medicine and are accordingly inherently distinctive.

28. Lilly promotes, advertises, and markets MOUNJARO® and ZEPBOUND® both to healthcare professionals and to patients, among others, through various channels, including on

the websites mounjaro.com, mounjaro.lilly.com, zepbound.com, and zepbound.lilly.com, in social media, in online advertisements, and on television.

29. As a result of Lilly's use, promotion, advertising, and marketing of MOUNJARO® and ZEPBOUND®, the Lilly Marks are exclusively associated with Lilly, serve to identify genuine Lilly products, and are valuable assets of Lilly.

THE RISKS OF COMPOUNDING

30. Upon information and belief, Defendant markets and sells to patients compounded drug products that purport to contain tirzepatide and that are not approved by the FDA or any other global regulatory agency ("Unapproved Compounded Drugs").

31. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (FDA guidance on drug compounding law compliance). This narrow exception applies, for instance, where a patient cannot safely take a commercially manufactured FDA-approved drug due to an allergy to a particular dye.

32. The Food, Drug, and Cosmetic Act (FDCA), in section 503A, prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not

required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this requirement to ensure that compounding pharmacies "are not actually operating as conventional manufacturers":

> The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A, [including that] compounding is for an identified individual patient, drugs compounded in advance of receiving prescriptions are compounded only in limited quantities, and drugs are distributed pursuant to a valid patient-specific prescription. These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry).

33. As the FDA further explained, "The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to []GMP requirements, are provided to a patient only based on individual patient need." *Id.* (emphasis in original).

34. Compounders are also limited in their ability to engage in a practice called anticipatory compounding, which is when, "based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician

will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or health care provider when a prescription for an identified individual patient is received." *Id.* As the FDA further explained:

> [A]nticipatory compounding [] has risks. For example, if a problem occurs during compounding, such as contaminating a drug product that is supposed to be sterile, or producing subpotent or superpotent sterile or non-sterile drugs, it could affect numerous patients, and not just one. Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination. Restricting anticipatory compounding to limited quantities serves to limit the number of patients likely to be affected if there are drug product mix-ups or contamination. The limitations on anticipatory compounding in section 503A (i.e., compounding must be in "limited quantities" and based on an "established relationship") help to protect patients from product quality issues. ***These limitations on anticipatory compounding also help to distinguish licensed pharmacists or licensed physicians compounding drug products under section 503A for individual patients from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription***.

Id. (emphasis added).

35. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients." The FDA has warned that: "Compounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed." https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated

compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries (FDA press announcement re guilty plea). At least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months, even though patients suffered near-immediate adverse events, including permanent blindness. https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (WFAA article re outbreak). One patient had believed "every pill you take, every shot you take is tested" and was surprised to learn that compounded drugs were neither fully tested nor deemed safe or otherwise approved by the FDA. *Id.*

37. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths. https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/us-illnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19 (U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001–19).

38. Lilly has seen problems first-hand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some contain bacteria, high impurity levels, different colors (pink, instead of colorless), or a chemical structure different from the tirzepatide in Lilly's FDA-approved medicines. In at least one instance, Lilly saw nothing more than sugar alcohol. Lilly also has

received reports of patients experiencing significant adverse events after being injected with non-Lilly tirzepatide, including a patient who experienced a seizure and was admitted to the Intensive Care Unit and other patients who experienced severe allergic reactions. According to the FDA's Adverse Events Reporting System (FAERS), to date, over 150 adverse events associated with compounded or so-called (but not actually) "generic" tirzepatide have been reported, including over 100 "serious cases" and at least 5 deaths.

39. Consequences from compounded drugs may be deadly. In October 2012, compounded drugs contaminated with a fungus were shipped throughout the country and later injected into patients' spines and joints. After these contaminated products were injected into nearly 14,000 patients, more than 60 people died of fungal meningitis. *Id.* Regarding this outbreak, the FDA has written:

> The 2012 fungal meningitis outbreak was not an isolated event. It was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs. In addition, many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then. And, because most compounders do not report adverse events to FDA, the agency may not be aware of adverse events associated with compounded drugs unless a health care provider submits an adverse event report regarding his or her patients or a state official notifies FDA.

https://www.fda.gov/media/102493/download (FDA Compounding Progress Report).

WIDESPREAD SAFETY CONCERNS ABOUT COMPOUNDED TIRZEPATIDE

40. Regulators and law enforcement across the United States and abroad have recognized the safety concerns with compounded tirzepatide and other incretins. They have issued warnings, and in at least one instance, banned incretin compounding.

41. The FDA, for example, has consistently and repeatedly raised its concerns with compounding generally and compounded incretins more specifically. https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry). The FDA specifically has targeted compounded tirzepatide as a threat to consumer safety. The Director of the FDA's Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products because they are not safe or effective. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024 (FDA warning letter re US Chem Labs); https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024 (FDA warning letter re Synthetix Inc. DBA Helix Chemical Supply).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists (Alabama Board of Medical Examiners press release). And the Maryland Poison Control Center warned that buying compounded incretins "online puts people at risk due to the medicine not being regulated and/or being sold from a source that is not licensed," including because those compounded products "have not

been evaluated for safety and effectiveness by the FDA." https://blog.mdpoison.com/2024/03/semaglutide (Blog of the Maryland Poison Center).

43. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®." https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products (Australia Minister for Health and Aged Care press release). As Mark Butler, Australia's Minister for Health, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives." *Id.*

44. Doctors and patient groups recognize the problems with compounded incretins, and they are sharing their concerns, too. The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association, for example, issued a joint statement warning that when people use incretin "alternatives, you may not be getting what you hoped for. You may also get something you did not want (other active substances have been found in some compounded versions)." https://www.obesityaction.org/wp-content/uploads/GLP-1-Compounded-Alternative-Statement_Final_Logos-1.pdf (joint statement from leading obesity expert organizations).

45. Lilly itself has issued multiple public warnings about compounded tirzepatide, including by publishing an open letter.

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

46. Lilly does not sell MOUNJARO® or ZEPBOUND® to Defendant for resale or redistribution. Nor has Lilly authorized Defendant to use the Lilly Marks in connection with any of Defendant's offered goods or services. On information and belief, therefore, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them to Defendant for prescription, administration, or other dispensing to patients.

47. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and has no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are ***not*** MOUNJARO® or ZEPBOUND®. Rather, Defendant passes off Unapproved Compounded Drugs as "generic Zepbound and generic Mounjaro." Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

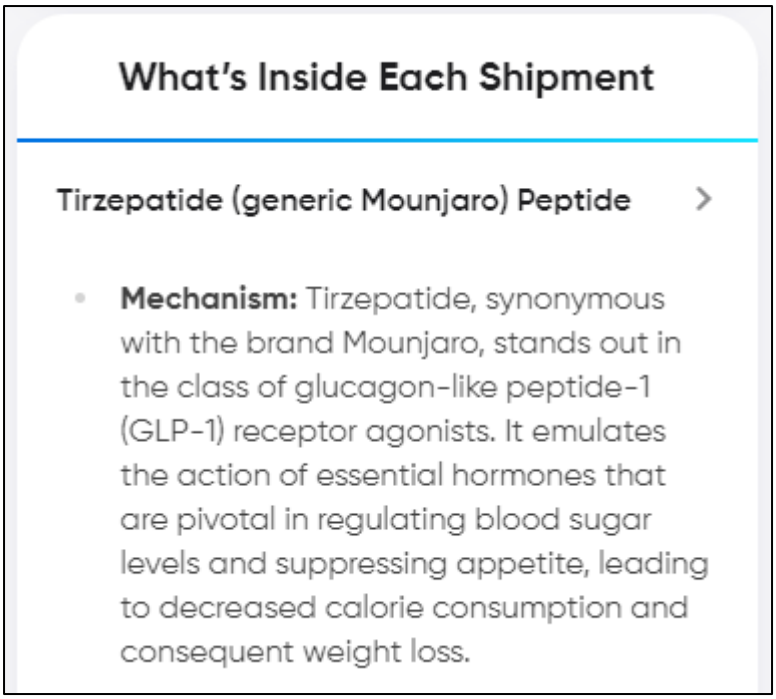
48. Because Defendant is not offering genuine MOUNJARO® or ZEPBOUND®, Lilly has no control over the safety, quality, or effectiveness of the Unapproved Compounded Drugs sold by Defendant.

49. Defendant also passes off as "generic Mounjaro" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

50. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

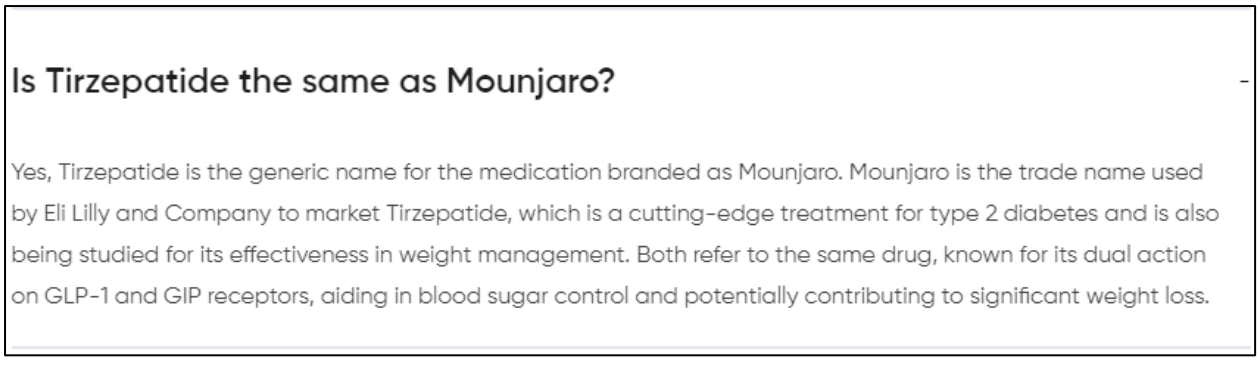
51. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website (hydramed.com/rx/tirzepatide), is shown below.

52. As the image shows, Defendant promotes its Unapproved Compounded Drugs as "Generic Zepbound & Mounjaro." Just below that, and as shown below, Defendant goes further, describing Tirzepatide as "synonymous with the brand Mounjaro."



53. Tirzepatide is not "synonymous with the brand Mounjaro;" tirzepatide is one among several ingredients in Lilly's MOUNJARO® and ZEPBOUND®.

54. Elsewhere on the same page, Defendant describes its Unapproved Compounded Drug as "known under the brand name Mounjaro." Defendant also provides a question-and-answer section that proclaims "Yes" "Tirzepatide [is] the same as Mounjaro," as shown below:



55. In this same paragraph, Defendant asserts that "Mounjaro is the trade name used by Eli Lilly and Company to market Tirzepatide"—rather than a federally registered trademark

used in connection with a medicine *containing* the active pharmaceutical ingredient tirzepatide—and that Defendant's capital-T "Tirzepatide" and MOUNJARO® "refer to the same drug."

56. On this "tirzepatide" webpage, which Defendant uses to sell its Unapproved Compounded Drugs, Defendant uses Lilly's coined terms MOUNJARO® and ZEPBOUND® at least 16 times, despite the fact that Defendant does not offer either of these Lilly medicines.

57. Defendant's website conveys the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or an FDA-approved "generic" version thereof. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution. Moreover, there are ***no*** "generic" versions of either MOUNJARO® and ZEPBOUND®.

58. Defendant first started using the Lilly Marks to advertise its Unapproved Compounded Drugs long after Lilly had adopted them. Defendant's use can only have been intended to benefit from the goodwill Lilly generated around the Lilly Marks.

59. Defendant also falsely advertises its Unapproved Compounded Drugs on its website by making statements that claim or imply that its Unapproved Compounded Drugs are FDA-approved and have been proven to achieve certain therapeutic outcomes. These statements rely on the FDA's approval of ***Lilly's*** medicines and clinical trials for ***Lilly's*** medicines. These studies and approvals have no bearing on, and cannot substantiate claims about, Defendant's Unapproved Compounded Drugs, which upon information and belief are sold without having undergone any clinical trials on safety and effectiveness.

60. For example, Defendant's same Tirzepatide webpage advertises that its Unapproved Compounded Drug is "an FDA-approved injectable medication utilized for weight management."

61. Defendant also cites to the results of clinical trials, including referring by name to Lilly's SURMOUNT® trials and stating that "individuals using Tirzepatide experienced notable weight reductions, some achieving weight loss that surpasses traditional benchmarks."

62. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** "FDA approved," are not "generic" forms of MOUNJARO® and/or ZEPBOUND®, were ***not*** subjected to clinical trials including Lilly's SURMOUNT® trials, and therefore are ***not*** clinically proven to achieve any results.

63. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website, to deceive patients who, upon information and belief, are seeking to buy but are in fact not buying genuine FDA-approved MOUNJARO® and/or ZEPBOUND® to treat their serious health conditions.

64. Defendant's prominent and misleading use of the Lilly Marks is likely to cause consumers to falsely believe that they are purchasing MOUNJARO® and/or ZEPBOUND®, that Defendant is a source for Lilly's FDA-approved treatment options MOUNJARO® and/or ZEPBOUND®, that Defendant's Unapproved Compound Drugs are as safe and effective as Lilly's FDA-approved treatment options MOUNJARO® and ZEPBOUND®, and/or that Defendant's services are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

65. Defendant's use of the Lilly Marks is without the permission, consent, or authorization of Lilly. Defendant has no right to use, and Defendant knows that it has no right to use, the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs or otherwise. Defendant's advertising and promotional materials are false and misleading where they suggest and/or state an association with Lilly's FDA-approved MOUNJARO® and ZEPBOUND®, because no such association exists.

66. There is no need for Defendant to use the Lilly Marks to advertise or promote its Unapproved Compounded Drugs purporting to contain tirzepatide, other than to trade upon the reputation of Lilly and to create confusion in the marketplace and/or mislead patients with serious health conditions regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

67. Defendant's unauthorized use of the Lilly Marks is not only intended to but likely to cause confusion, to cause mistake, or to deceive, and infringes Lilly's established exclusive rights in the Lilly Marks.

68. Upon information and belief, unless enjoined by this Court, Defendant will continue to use the Lilly Marks and/or otherwise falsely advertise its Unapproved Compounded Drugs as associated with or being MOUNJARO® and ZEPBOUND®, all in violation of Lilly's rights.

HARM TO THE PEOPLE OF COLORADO AND LILLY

69. Lilly's FDA-approved MOUNJARO® and ZEPBOUND® medications have undergone extensive clinical trials and approval processes. But these clinical studies and FDA approvals only apply to genuine Lilly MOUNJARO® and ZEPBOUND® used as directed by a

prescribing physician. The clinical trials and approval processes do not inform the safety, quality, or effectiveness of Defendant's Unapproved Compounded Drugs.

70. Defendant's unlawful, misleading business model may expose patients to the serious risks described above. Critically, because Defendant falsely advertises and, without Lilly's consent, uses the Lilly Marks in connection with its Unapproved Compounded Drugs, patients are unlikely to know the unique risks associated with Defendant's untested, unapproved drugs.

71. Defendant advertises itself as providing MOUNJARO® and ZEPBOUND® (or their supposed "generic" equivalents), when in reality Defendant provides untested Unapproved Compounded Drugs. Defendant's promotional tactics are ***intended*** to mislead patients into believing that Unapproved Compounded Drugs are backed by clinical trials and have been approved by the FDA, when no such studies have been conducted, and neither the FDA nor any other regulatory body has approved them. Patients who take Defendant's Unapproved Compounded Drugs and suffer harm will have had no forewarning.

72. Not only does this deceitful content expose the people of Colorado to serious health risks, but Defendant's unlawful tactics undermine the name, goodwill, and reputation that Lilly has invested heavily in developing. Moreover, Defendant's unfair methods allow it and its suppliers of Unapproved Compounded Drugs to unjustly profit from sales to patients looking for MOUNJARO® and ZEPBOUND®.

FIRST CAUSE OF ACTION
Trademark Infringement
in Violation of 15 U.S.C. § 1114

73. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

74. Lilly is the owner of all right, title, and interest in federal trademark registrations for the inherently distinctive Lilly Marks and has standing to maintain an action for trademark infringement under 15 U.S.C. § 1114.

75. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

76. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive, and thus constitute trademark infringement of the registered Lilly Marks, in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114.

77. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful.

78. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's conduct, unless enjoined by

the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

79. This is an exceptional case under 15 U.S.C. § 1117.

80. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

SECOND CAUSE OF ACTION
Trademark Infringement, False Designation of Origin and Unfair Competition in Violation of 15 U.S.C. § 1125

81. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

82. Lilly is the owner of all right, title, and interest in the inherently distinctive Lilly Marks and has standing to maintain an action for trademark infringement, false designation of origin, and unfair competition under 15 U.S.C. § 1125.

83. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

84. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute trademark infringement, false designation of origin,

and unfair competition with respect to the Lilly Marks, in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).

85. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful.

86. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's conduct, unless enjoined by the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

87. This is an exceptional case under 15 U.S.C. § 1117.

88. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

THIRD CAUSE OF ACTION
False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

89. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

90. Defendant's commercial advertising claims described herein are false and misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

91. Defendant has knowingly and willfully made material false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs, and these statements regarding Unapproved Compounded Drugs' safety, quality, effectiveness, and

regulatory status have influenced and are likely to continue to influence consumers' purchasing decisions.

92. Defendant's statements—including its various literally false claims—have the tendency to deceive a substantial segment of consumers, who have relied or likely will rely on Defendant's false statements in making their tirzepatide-based medicine purchase decisions.

93. Defendant has caused its false statements to enter interstate trade or commerce.

94. As a direct and proximate result of Defendant's false and deceptive campaign, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.

95. As a direct and proximate result of Defendant's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the direct diversion of sales from Lilly to Defendant and Defendant's suppliers and by a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® and the Lilly Marks.

96. This is an exceptional case under 15 U.S.C. § 1117.

97. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

FOURTH CAUSE OF ACTION
Deceptive Trade Practices
in Violation of C.R.S. § 6-1-101 *et seq*.

98. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

99. The above-described acts of Defendant constitute deceptive trade practices in violation C.R.S. § 6-1-101 *et seq.*

100. Among other things, C.R.S. § 6-1-105 defines actions that constitute a "deceptive trade practice" as including, but not limited to, when a person, in the course of the person's business, vocation, or occupation, does the following:

(a) Either knowingly or recklessly passes off goods, services, or property as those of another;

(b) Either knowingly or recklessly makes a false representation as to the source, sponsorship, approval, or certification of goods, services, or property;

(c) Either knowingly or recklessly makes a false representation as to affiliation, connection, or association with or certification by another;

* * *

(e) Either knowingly or recklessly makes a false representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith;

* * *

(g) Represents that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another;

* * *

(i) Advertises goods, services, or property with intent not to sell them as advertised;

* * *

(u) Fails to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction.

101. As set forth herein, Defendant's actions fit within the scope of C.R.S. § 6-1-105.

102. Evidence that Defendant has engaged in these deceptive trade practices is prima facie evidence of Defendant's intent to injure competitors and to destroy or substantially lessen competition under C.R.S. § 6-1-105(2).

103. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

104. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of C.R.S. § 6-1-101 *et seq.*

105. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful with the intent to deceive.

106. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be

important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

107. Because Defendant conducts sales online, a significant number of Defendant's consumers will encounter Defendant's services via Defendant's website, on which Defendant engages in trademark infringement and false advertising.

108. Because Defendant's misrepresentations are advertised directly to the public as potential or actual consumers, a significant public impact is presumed.

109. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been injured and damaged and will continue to be injured and damaged, making Defendant liable to Lilly under C.R.S. § 6-1-113.

110. Under C.R.S. § 6-1-113, Defendant is liable to Lilly for damages, including treble damages, as a result of Defendant's bad faith conduct. In addition, Lilly is entitled to attorneys' fees and costs.

111. Defendant's conduct, unless enjoined by the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

112. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

113. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief.

FIFTH CAUSE OF ACTION
Trademark Infringement and Unfair Competition in Violation of Colorado Common Law

114. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

115. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Colorado common law.

116. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks to pass off its Unapproved Compounded Drugs purporting to contain tirzepatide as genuine MOUNJARO® and ZEPBOUND®.

117. Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services is likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant.

118. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

119. Defendant's actions thereby unfairly and wrongfully exploit and infringe Lilly's trademark, goodwill, and reputation.

120. As a direct and proximate result of Defendant's trademark infringement and unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the direct diversion of sales from Lilly to

Defendant and by a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

121. By reason of Defendant's acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Lilly is entitled to entry of preliminary and permanent injunctive relief in addition to monetary damages.

JURY DEMAND

Plaintiff Lilly hereby demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in its favor on each and every claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that Defendant:

   a. Infringed the federally registered Lilly Marks, in violation of 15 U.S.C. § 1114(1);

   b. Infringed the Lilly Marks and engaged in trademark infringement, false designation of origin, and unfair competition, in violation of 15 U.S.C. § 1125(a)(1)(A);

   c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B);

   d. Engaged in deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of C.R.S. §§ 6-1-101 *et seq*. and in violation of the common law of Colorado; and

e. That each of the above acts was willful and knowing.

2. An injunction preliminarily and then permanently enjoining and restraining Defendant and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:

a. Using the Lilly Marks or any mark confusingly similar to them, in connection with the advertising, promoting, marketing, selling or offering for sale of any goods or services (including, but not limited to, Unapproved Compounded Drugs) or otherwise engaging in any activity that is likely to cause confusion, cause mistake, or deceive or otherwise infringe any rights of Plaintiff Lilly in the Lilly Marks or any similar mark;

b. Falsely stating or suggesting that Defendant's Unapproved Compounded Drugs are genuine or generic versions of MOUNJARO® or ZEPBOUND®, that Defendant is associated or connected in any way with Plaintiff or its products, or that Defendant's Unapproved Compounded Drugs are approved by the FDA, have been the subject of clinical studies, or achieve certain therapeutic outcomes;

c. Engaging in any unfair competition with Plaintiff Lilly; and

d. Engaging in any deceptive or unfair acts.

3. An Order Requiring Defendant and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that Defendant is not and never has been

authorized by, affiliated with, sponsored by, approved by, or related to Plaintiff Lilly or MOUNJARO® and ZEPBOUND®, that Defendant's Unapproved Compounded Drugs are not MOUNJARO® or ZEPBOUND®, that Defendant's Unapproved Compounded Drugs are not generic MOUNJARO® or generic ZEPBOUND®, that Defendant's Unapproved Compounded Drugs have never been genuine or generic versions of MOUNJARO® and ZEPBOUND®, and that Defendant's Unapproved Compounded Drugs are not and have never been approved or reviewed by the FDA or tested for safety, quality, or effectiveness in clinical trials.

4. An Order directing Defendant to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which they have complied with the Court's injunction.

5. An Order requiring Defendant to account for and pay to Lilly any and all profits arising from the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

6. An Order requiring Defendant to pay Lilly compensatory damages in an amount as yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition, and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws.

7. An Order for pre-judgment and post-judgment interest on all damages.

8. An Order requiring Defendant to pay Lilly all types of monetary remedies available under Colorado state law in amounts as yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, Colorado state law, and any other applicable provision of law.

10. Other relief as the Court may deem appropriate.

Dated: June 20, 2024

Respectfully submitted,

/s/ Daniel N. Guisbond

Daniel N. Guisbond
Emily P. Linehan
WHEELER TRIGG O'DONNELL LLP
370 Seventeenth Street, Suite 4500
Denver, Colorado 80202
Telephone: (303) 244-1800
Facsimile: (303) 244-1879
guisbond@wtotrial.com
linehan@wtotrial.com

Joshua L. Simmons (application for admission forthcoming)
Jeanna M. Wacker (application for admission forthcoming)
Ashley Ross (application for admission forthcoming)
Joshua C. Berlowitz (application for admission forthcoming)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900
joshua.simmons@kirkland.com
jeanna.wacker@kirkland.com
ashley.ross@kirkland.com
josh.berlowitz@kirkland.com

Diana M. Watral (application for admission forthcoming)
James F. Hurst (application for admission forthcoming)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, Illinois 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
diana.watral@kirkland.com
james.hurst@kirkland.com

Attorneys for Plaintiff
ELI LILLY AND COMPANY

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 20, 2024, I electronically filed the foregoing **COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN, AND DECEPTIVE TRADE PRACTICES** with the Clerk of the Court using the CM/ECF system.

/s/ Daniel N. Guisbond

EXHIBIT A

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 6,809,369

Registered Aug. 02, 2022

Int. Cl.: 5

Trademark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of diabetes

FIRST USE 6-3-2022; IN COMMERCE 6-3-2022

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 88-680,946, FILED 11-05-2019

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 7,068,463

Registered May 30, 2023

Int. Cl.: 44

Service Mark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 44: Medical information services in the field of diabetes

FIRST USE 6-7-2022; IN COMMERCE 6-7-2022

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 97-468,410, FILED 06-21-2022

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

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United States of America
United States Patent and Trademark Office

ZEPBOUND

Reg. No. 7,288,373

Registered Jan. 23, 2024

Int. Cl.: 5

Trademark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of obesity

FIRST USE 11-30-2023; IN COMMERCE 11-30-2023

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 97-362,818, FILED 04-14-2022

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

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EXHIBIT B

HydraMed
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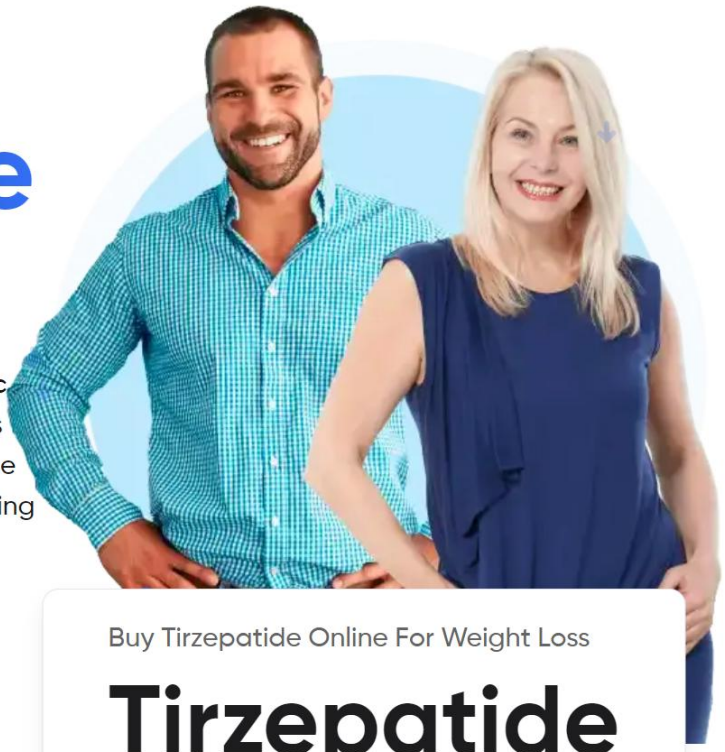

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Tirzepatide

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The team is incredibly patient and helpful, making sure all my questions are answered...

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The convenience of HydraMed's telehealth service has been fantastic, especially with their quick...

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K. Sharma

Grateful to HydraMed for the outstanding care and ease of scheduling. The staff is knowledgeable...

N. Gray

Your current weight in pounds

weight in .lbs

CALCULATE

How much could you lose?

In the SURMOUNT clinical trials, participants taking Tirzepatide experienced an average weight loss of up to 52 pounds, representing around 20% of their body weight.

Purchase Tirzepatide Generic Zepbound & Mounjaro

When you buy Tirzepatide online, the generic for Mounjaro and Zepbound, through HydraMed, you gain access to a dedicated team of caring nurses and doctors committed to creating a customized weight management plan for you. Rest assured, you're receiving the highest quality Tirzepatide sourced from our US-based, FDA-registered pharmacy. Embark on your journey to a happier, healthier self with the support of HydraMed.

What's Inside Each Shipment

Tirzepatide (generic Mounjaro) Peptide

- **Mechanism:** Tirzepatide, synonymous with the brand Mounjaro, stands out in the class of glucagon-like peptide-1 (GLP-1) receptor agonists. It emulates the action of essential hormones that are pivotal in regulating blood sugar levels and suppressing appetite, leading to decreased calorie consumption and consequent weight loss.
- **Clinical Insights:** Research on Tirzepatide showcases its superior potency in weight management, with studies indicating it may outperform Semaglutide, offering significant weight loss—potentially exceeding 20%. Its proven effectiveness in clinical trials marks it as a standout option, yielding greater weight loss percentages than many conventional treatments.

Supplies

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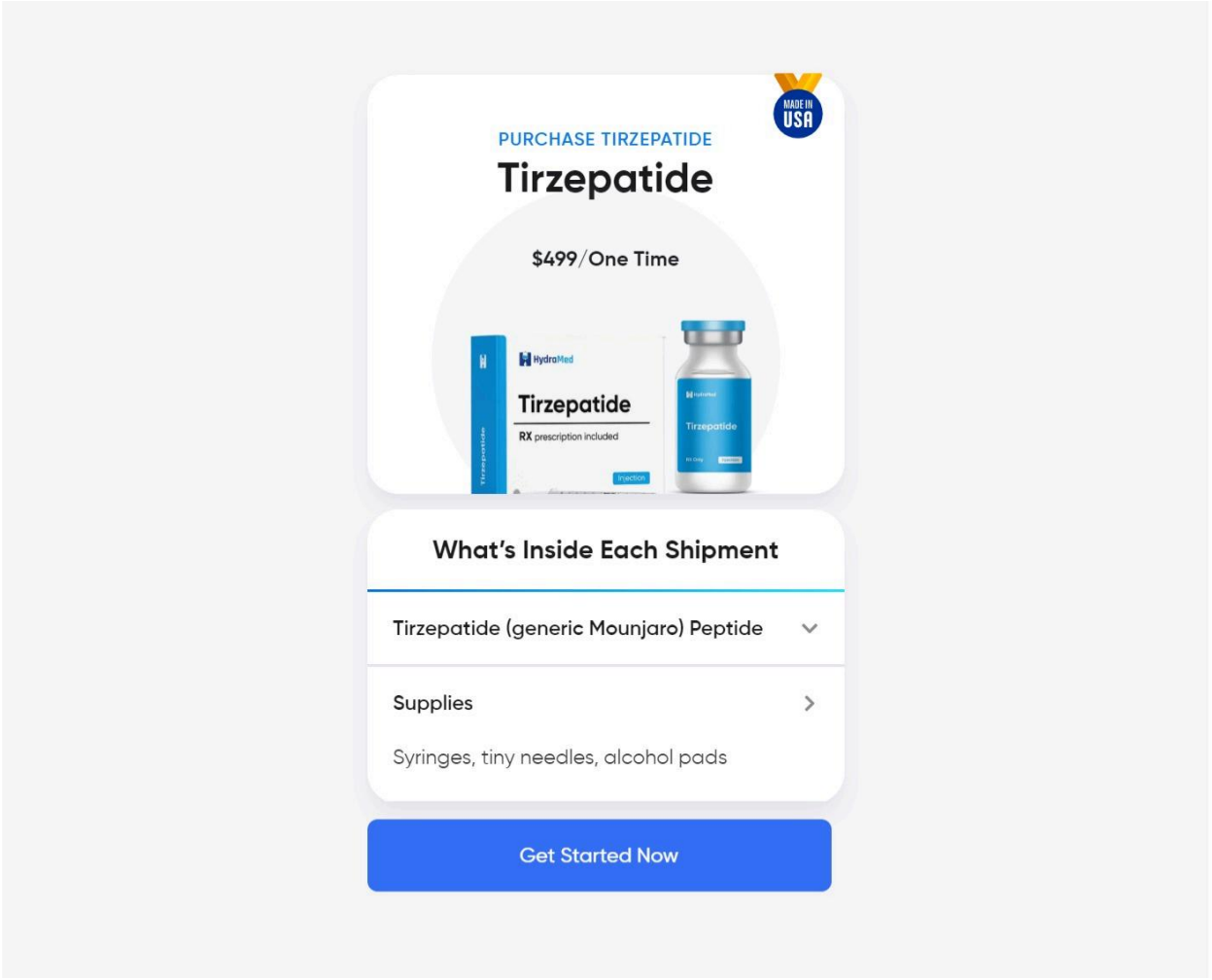
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Injection
Tirzepatide
What's Inside Each Shipment
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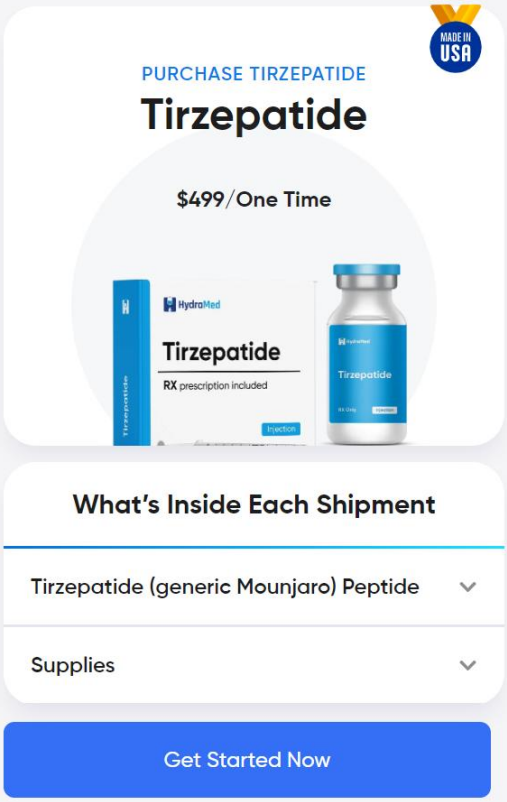

HydraMed Weight Loss Program

The Tirzepatide weight management program at HydraMed is designed as a comprehensive, extended plan aimed at assisting you in achieving significant weight loss over several months. If you're looking for a substantial shift in your weight loss journey, this program could be your pathway to success.

Tirzepatide, known under the brand name Mounjaro, is an FDA-approved injectable medication utilized for weight management. In clinical studies, individuals using Tirzepatide experienced notable weight reductions, some achieving weight loss that surpasses traditional benchmarks.

Subscription Includes:

- Virtual meetings with our medical team as needed
- Delivery of the Tirzepatide weight loss injection kit

The Process

Start by completing your order on our website, detailing your health objectives and history. Our medical team will then evaluate your submission and, upon approval, process your order, providing you with your HydraMed Tirzepatide prescription along with precise self-injection instructions. As a subscriber, you'll enjoy ongoing support from our healthcare experts and reliable delivery of your injection kits.

Support

Subscribers are offered direct video sessions with a medical professional and monthly check-ins with a designated HydraMed coach, ensuring continuous guidance throughout their journey.

Side Effects

Tirzepatide side effects, like those of many medications, can vary. While some are common and typically mild, others are rare but potentially severe. It's important to be aware of these side effects to ensure the safe use of Tirzepatide.

Common Side Effects:

- Gastrointestinal Issues: Nausea, diarrhea, vomiting, constipation, abdominal pain
- Appetite Changes: Decreased hunger
- Fatigue: Feeling unusually tired

Less Common Side Effects:

- Pancreatitis: Severe abdominal pain, nausea, vomiting
- Hypoglycemia: Shaking, sweating, fast heartbeat, dizziness, confusion
- Kidney Problems: Rare, but requires regular monitoring

Tirzepatide | Mounjaro | Weight Loss | Fat Burn | Peptide | zepbound

STRESS-FREE ENROLLMENT STARTS HERE

Buy Tirzepatide Simply with HydraMed

HydraMed makes it easy to get the treatment you need from the comfort of your home.

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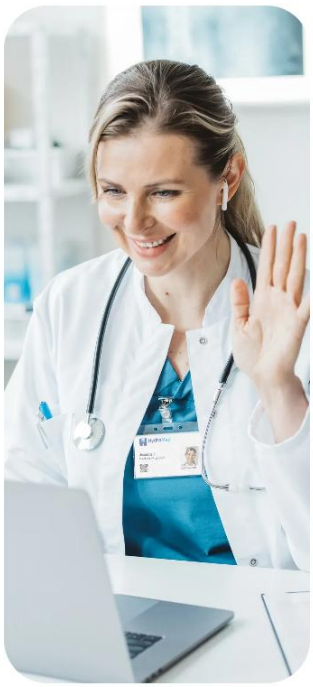
- FDA registered pharmacy



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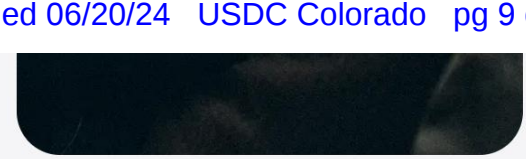

★★★★★

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K. Sharma

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Grateful to HydraMed for the outstanding care and ease of scheduling. The staff is knowledgeable...

N. Gray

★★★★★

The professionalism and ease of getting my needs met remotely have been fantastic.

M. Quinn

Science Backed. Doctor Approved.

All of HydraMed's programs use the most up-to-date medical knowledge to give you the best results possible.

Meet Your Medical Team!

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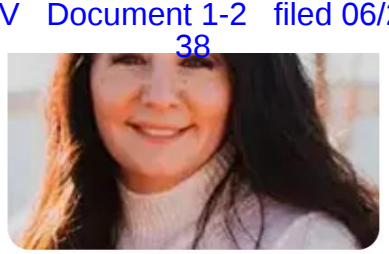
Thomas Paluska, MD

NURSE PRACTITIONER

Courtney Williams, FNP



Tirzepatide FAQs

What is Tirzepatide?

Tirzepatide is a groundbreaking medication tailored for weight management and blood sugar control, especially beneficial for individuals with obesity or Type 2 diabetes. It's unique as it combines the actions of GLP-1 and GIP receptors, amplifying its effectiveness in reducing appetite and enhancing insulin secretion, which in turn facilitates significant weight loss and improved glycemic control.

How does Tirzepatide work?

How does Tirzepatide work for weight loss?

Is Tirzepatide the same as Mounjaro?

Is compounded Tirzepatide safe?

What is the difference between Semaglutide and Tirzepatide?

Which is better, Semaglutide or Tirzepatide?

Can I switch from Semaglutide to Tirzepatide?

How frequently should one administer Tirzepatide?

What is Tirzepatide?

+

How does Tirzepatide work?

-

Tirzepatide functions by mimicking the effects of incretin hormones, specifically GLP-1 and GIP, which play pivotal roles in regulating blood sugar and appetite. Its dual-action mechanism promotes a feeling of fullness, decreases appetite, and improves insulin secretion, all contributing to effective weight management and glycemic control.

How does Tirzepatide work for weight loss?

+

Is Tirzepatide the same as Mounjaro?

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+

What determines if I qualify for a Tirzepatide prescription?

+

What is Tirzepatide?

How does Tirzepatide work?

How does Tirzepatide work for weight loss?

Tirzepatide aids in weight loss by simultaneously activating GLP-1 and GIP receptors, key hormones involved in regulating hunger and insulin secretion. This dual-action approach helps reduce appetite, decrease caloric intake, and improve the body's ability to manage blood sugar levels, leading to significant weight reduction and enhanced metabolic health. The medication's ability to influence these pathways makes it a potent tool in achieving sustained weight loss, particularly when combined with lifestyle modifications like diet and exercise.

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Is Tirzepatide the same as Mounjaro?

Yes, Tirzepatide is the generic name for the medication branded as Mounjaro. Mounjaro is the trade name used by Eli Lilly and Company to market Tirzepatide, which is a cutting-edge treatment for type 2 diabetes and is also being studied for its effectiveness in weight management. Both refer to the same drug, known for its dual action on GLP-1 and GIP receptors, aiding in blood sugar control and potentially contributing to significant weight loss.

Is compounded Tirzepatide safe?

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What is Tirzepatide? +

How does Tirzepatide work? +

How does Tirzepatide work for weight loss? +

Is Tirzepatide the same as Mounjaro? +

Is compounded Tirzepatide safe? -

Compounded Tirzepatide, when prepared in a licensed, FDA-registered pharmacy under strict quality controls, is safe. However, it's crucial to use it under medical supervision to ensure its efficacy and safety, tailoring the treatment to the individual's health needs and monitoring for any adverse reactions.

What is the difference between Semaglutide and Tirzepatide? +

Which is better, Semaglutide or Tirzepatide? +

Can I switch from Semaglutide to Tirzepatide? +

How frequently should one administer Tirzepatide? +

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How does Tirzepatide work? +

How does Tirzepatide work for weight loss? +

Is Tirzepatide the same as Mounjaro? +

Is compounded Tirzepatide safe? +

What is the difference between Semaglutide and Tirzepatide? -

The key difference lies in their mechanisms; while both are incretin mimetics, Semaglutide is a GLP-1 receptor agonist, whereas Tirzepatide simultaneously acts on both GLP-1 and GIP receptors. This dual action potentially makes Tirzepatide more effective in promoting weight loss and improving glycemic control.

Which is better, Semaglutide or Tirzepatide? +

Can I switch from Semaglutide to Tirzepatide? +

How frequently should one administer Tirzepatide? +

What determines if I qualify for a Tirzepatide prescription? +

What is Tirzepatide?

How does Tirzepatide work?

How does Tirzepatide work for weight loss?

Is Tirzepatide the same as Mounjaro?

Is compounded Tirzepatide safe?

What is the difference between Semaglutide and Tirzepatide?

Which is better, Semaglutide or Tirzepatide?

Determining which is better depends on individual health goals, existing conditions, and how one's body responds to treatment. Tirzepatide might offer superior benefits for some due to its dual incretin receptor action, leading to significant weight loss and improved blood sugar levels, but a healthcare provider can best assess which medication suits your specific needs.

Can I switch from Semaglutide to Tirzepatide?

How frequently should one administer Tirzepatide?

What determines if I qualify for a Tirzepatide prescription?

What is Tirzepatide? +

How does Tirzepatide work? +

How does Tirzepatide work for weight loss? +

Is Tirzepatide the same as Mounjaro? +

Is compounded Tirzepatide safe? +

What is the difference between Semaglutide and Tirzepatide? +

Which is better, Semaglutide or Tirzepatide? +

Can I switch from Semaglutide to Tirzepatide? -

Switching from Semaglutide to Tirzepatide is possible and might be beneficial for certain individuals seeking enhanced weight loss results or improved glycemic control. However, this switch should always be done under the guidance of a healthcare professional to ensure a smooth transition and to tailor the dosage to your specific health requirements.

How frequently should one administer Tirzepatide? +

What determines if I qualify for a Tirzepatide prescription? +

What is Tirzepatide? +

How does Tirzepatide work? +

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Can I switch from Semaglutide to Tirzepatide? +

How frequently should one administer Tirzepatide? -

Tirzepatide is generally administered once weekly through a subcutaneous injection. The dosage and frequency will be personalized based on your medical condition, treatment goals, and response to therapy, as determined by your healthcare provider.

What determines if I qualify for a Tirzepatide prescription? +

What is Tirzepatide? +

How does Tirzepatide work? +

How does Tirzepatide work for weight loss? +

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Can I switch from Semaglutide to Tirzepatide? +

How frequently should one administer Tirzepatide? +

What determines if I qualify for a Tirzepatide prescription? -

Eligibility for a Tirzepatide prescription typically involves an assessment of your health status, weight management goals, and any potential contraindications. While many individuals may qualify, it's essential to undergo a thorough medical evaluation to ensure Tirzepatide is an appropriate and safe option for you.

What determines if I qualify for a Tirzepatide prescription? +

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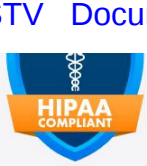

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UPDATE
April 28, 2024

What is Tirzepatide and How Can it Help You Lose Weight?

Key Points

- **Dual-Action Approach:** Tirzepatide targets both GIP and GLP-1 receptors, providing a unique dual-action mechanism for enhanced weight loss.
- **Superior Weight Loss Outcomes:** Clinical trials show that tirzepatide leads to greater weight loss compared to existing therapies, offering significant results.
- **FDA-Approved for Safety and Efficacy:** Tirzepatide is approved by the FDA, ensuring it meets rigorous safety and efficacy standards. This approval provides confidence in its use for weight loss and diabetes management, backed by extensive clinical trials and scientific validation.

Tirzepatide is a breakthrough medication that has gained attention for its potential to assist with weight loss. It's an injectable drug originally designed to help control blood sugar in people with type 2 diabetes, but its effects on weight loss have made it popular in the health and fitness community. Tirzepatide, also known as the generic version of Mounjaro, can be seen as a dual-purpose medication—one that can manage diabetes and aid in losing weight.

As a peptide, Tirzepatide belongs to a class of molecules made up of amino acids linked together, which mimic natural hormones in the body to regulate physiological functions like appetite and insulin secretion.

How Does Tirzepatide Work for weight loss?

Tirzepatide operates as a dual incretin receptor agonist, targeting two specific hormones: glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). These hormones are integral to controlling blood sugar levels and regulating appetite. When you use tirzepatide, it signals to your brain that you're full, which helps suppress appetite and reduce cravings. This is why it's been effective in supporting weight loss efforts, as it makes it easier to maintain a calorie-controlled diet.

Tirzepatide and Weight Loss

Tirzepatide's ability to reduce hunger is a significant reason it has gained traction in the weight loss community. In clinical trials, participants using tirzepatide experienced considerable weight loss, especially when paired with a balanced diet and regular exercise. The drug's dual action on blood sugar control and appetite suppression gives it an edge over other weight loss treatments. By keeping your appetite in check, tirzepatide makes it easier to resist those extra snacks and stay on track with your weight loss goals.

The Dual Action of Tirzepatide

What sets tirzepatide apart is its ability to address both weight loss and diabetes management. Its dual action on GLP-1 and GIP not only reduces appetite but also helps with insulin secretion, offering a unique approach to managing type 2 diabetes and promoting weight loss. This versatility makes

tirzepatide a valuable addition to the arsenal of medications for those seeking a multi-faceted approach to health.

Tirzepatide's Broader Impacts

Tirzepatide has a broader impact beyond just weight loss, especially for individuals with type 2 diabetes. By mimicking hormones that regulate insulin secretion, it offers a unique benefit, making it a versatile choice for those dealing with both diabetes and obesity. Tirzepatide's dual-action mechanism helps promote healthier eating habits, leading to better blood sugar management and ultimately contributing to improved health outcomes.

Medication Mechanism of Action

Medication	Mechanism of Action
Tirzepatide	Dual GIP and GLP-1 receptor agonist
Semaglutide	GLP-1 receptor agonist
Retatrutide	Tri-agonist (GLP-1, GIP, and glucagon)

How Tirzepatide Is Administered by Subcutaneous Injection

Tirzepatide is administered through a subcutaneous (SubQ) injection, a method where the medication is injected just below the skin's surface. This process is straightforward and uses a small needle, similar to those employed for insulin injections. The injection sites are typically the abdomen, thigh, or upper arm, allowing for easy self-administration. Healthcare professionals often train patients on proper injection techniques to ensure safe and effective use. This method provides a convenient way to deliver the medication, making it a practical option for many users.

Generic Tirzepatide Is An Affordable Alternative to Mounjaro and Zepbound

Mounjaro and Zepbound are popular brand names for tirzepatide, a medication used for weight loss and diabetes management. However, there are generic versions that offer the same benefits at a more affordable price. Think of these generics as the store-brand equivalent—they deliver the same results but at a lower cost. This budget-friendly approach makes tirzepatide more accessible, allowing

a broader range of people to benefit from its potential.

Expanding Access to Tirzepatide with Generic Options

With generic versions of Mounjaro and Zepbound, tirzepatide becomes accessible to a wider audience. This increased accessibility can play a significant role in supporting individuals on their weight loss journey. By choosing a generic option, you get the same efficacy and safety profile as the brand names, with added cost savings. This can make a substantial difference for those seeking effective weight loss solutions without straining their budgets.

How Tirzepatide Stands Out from Other Treatments

What sets tirzepatide apart from other weight loss medications is its dual-targeting mechanism. While many other treatments, like semaglutide, focus solely on GLP-1 receptors, tirzepatide activates both GLP-1 and GIP receptors, creating a more comprehensive effect on weight loss. This dual action allows tirzepatide to produce enhanced results by leveraging the combined impact of these hormones.

In contrast, retatrutide, a newer medication, has a tri-agonist approach, targeting GLP-1, GIP, and glucagon. This multi-targeted mechanism offers even broader metabolic effects, highlighting the ongoing evolution of weight loss treatments and the versatility of these medications in managing obesity and related conditions.

The Science Behind Tirzepatide's Development

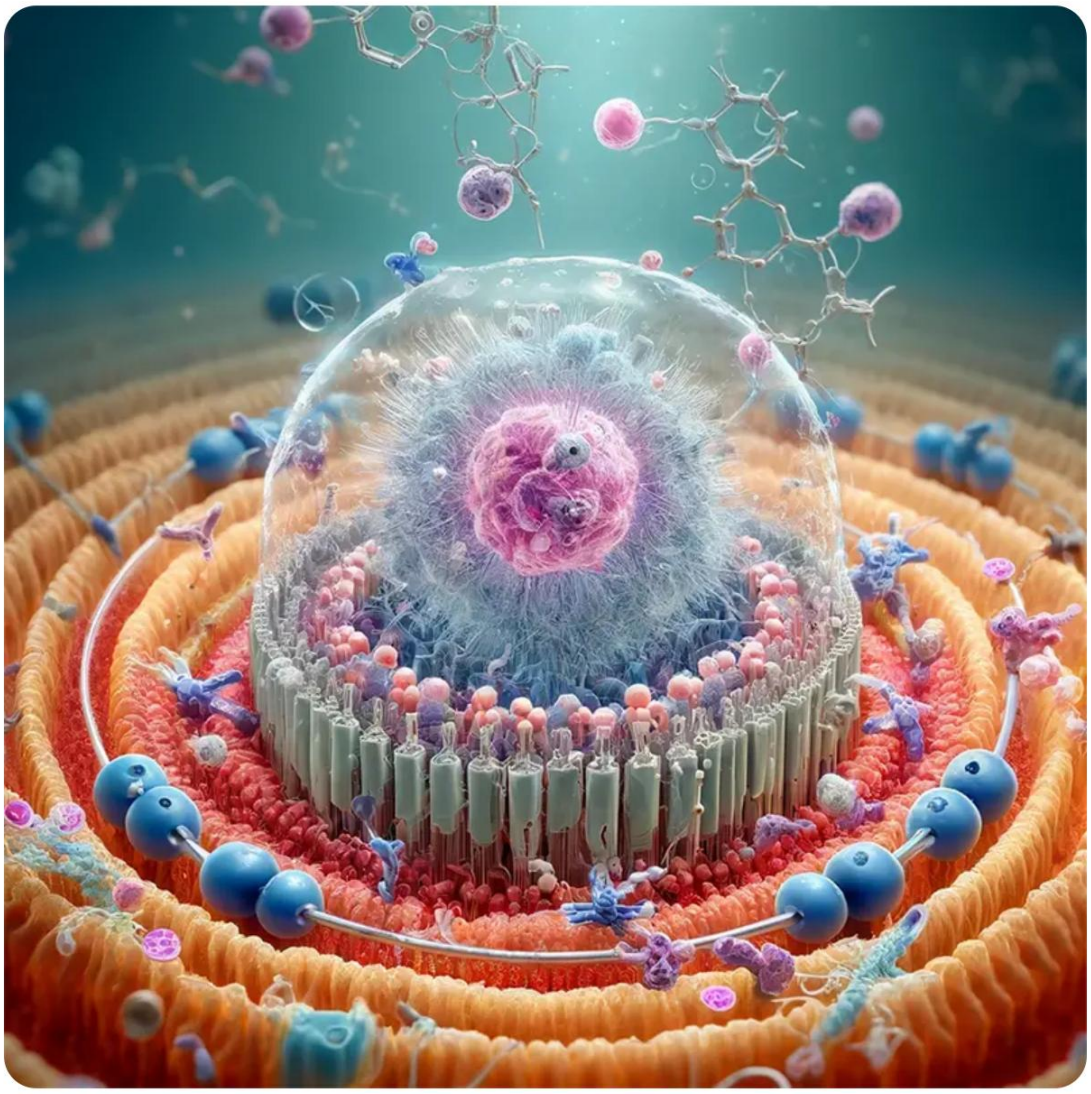
Tirzepatide's development is grounded in extensive scientific research focusing on incretin hormones and their role in metabolism and body weight regulation. Researchers discovered that two hormones, glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), play key roles in regulating blood sugar and appetite. By studying the complex interactions between these hormones and various metabolic processes, scientists engineered tirzepatide to target both simultaneously.

Using advanced peptide synthesis techniques, tirzepatide was designed to bind and activate both GLP-1 and GIP receptors. This dual-action approach provides a unique therapeutic option, allowing for greater efficacy in weight loss compared to treatments that focus on a single receptor.

The Mechanism of Action

Tirzepatide's effectiveness lies in its ability to mimic the natural incretin hormones, GIP and GLP-1. By binding to both receptors, tirzepatide triggers a cascade of physiological responses that promote weight loss and improve metabolic health.

When tirzepatide is administered, it acts on the GLP-1 and GIP receptors, which are critical in regulating appetite, insulin secretion, and blood sugar levels. This dual action slows gastric emptying, reduces calorie intake, and enhances insulin sensitivity. These effects not only support weight loss but also contribute to better blood sugar control, a crucial benefit for individuals with type 2 diabetes.



In the image, the cellular structure provides a setting where tirzepatide, a GLP-1 receptor agonist, operates. Here's a step-by-step explanation of what happens and how it contributes to weight loss:

- **Cell and Receptors**: The cell's structure, seen in the illustration, contains receptor sites on its outer membrane. These sites are specific proteins that can bind with certain molecules, like tirzepatide.
- **Binding Process**: The smaller entities in the image represent molecules like tirzepatide. This GLP-1 receptor agonist is designed to attach to glucagon-like peptide-1 (GLP-1) receptors on the cell's membrane.
- **Cellular Response**: When tirzepatide binds to a GLP-1 receptor, it initiates a series of signals within the cell. This cascade of signals can trigger various effects, depending on the type of cell and its location. In the context of weight loss, activating GLP-1 receptors can help in several ways:
  - **Reduced Appetite**: Activation of these receptors can send signals to the brain that lead to decreased hunger and increased feelings of fullness.
  - **Slower Gastric Emptying**: GLP-1 receptor activation can slow down the rate at which food

leaves the stomach, contributing to prolonged satiety.

- **Improved Insulin Response**: GLP-1 receptors can also enhance insulin secretion, which helps regulate blood sugar levels and may indirectly influence fat storage and metabolism.

This image visually represents these key interactions, showing the binding process and the internal signaling that follows, leading to physiological responses that can contribute to weight loss.

Impact on Appetite and Metabolism

Tirzepatide significantly affects appetite regulation by stimulating the GIP and GLP-1 receptors in the brain, leading to a reduction in hunger and an increase in feelings of fullness. This results in naturally consuming fewer calories, aiding in sustained weight loss over time.

Additionally, tirzepatide enhances metabolic function. It increases insulin sensitivity, boosts fat burning, and optimizes energy expenditure. This comprehensive impact on metabolism creates a favorable environment for consistent weight loss and contributes to a healthier body mass index (BMI).

Long-Term Benefits for Weight Management

One of the key advantages of tirzepatide is its potential to deliver long-term benefits. By addressing both appetite regulation and metabolic function, tirzepatide helps set a new weight set point, making it easier to maintain weight loss achievements. The medication's dual-action mechanism contributes to improved insulin sensitivity, reduced inflammation, and a lower risk of obesity-related complications, such as cardiovascular disease and type 2 diabetes.

Investing in tirzepatide as a long-term weight loss solution not only impacts physical appearance but also supports overall health and well-being. The reduced risk of obesity-related health issues can lead to a longer, healthier life.

Clinical Trials and Their Impactful Results

Tirzepatide's efficacy and safety have been validated through a series of rigorous clinical trials, providing a robust foundation for its clinical application. The trials followed a multi-phase approach to determine the optimal dosage, assess tolerability, and evaluate long-term outcomes.

Overview of the Trial Phases

Initial trials focused on determining the best dose for tirzepatide and evaluating its tolerability. As the trials advanced to larger studies, researchers collected extensive data on tirzepatide's weight loss outcomes and long-term effects. This comprehensive approach ensured that the medication met high safety and efficacy standards.

Key Findings from the Research

The phase 3 SURMOUNT-1 trial demonstrated tirzepatide's exceptional weight loss efficacy. Participants who received the highest dose achieved an average weight loss of 22.5% after 72 weeks. This substantial result underscores tirzepatide's potential as a game-changer in obesity management.

Furthermore, the clinical trials showed that tirzepatide improved metabolic health markers, including reduced blood sugar levels, lower blood pressure, and decreased cholesterol. These results highlight the broader benefits of tirzepatide beyond weight loss, reinforcing its position as a promising treatment option for individuals with type 2 diabetes and those seeking sustainable weight management solutions.Participant Testimonials and Success Stories

The transformative power of tirzepatide is best illustrated through the success stories of clinical trial participants. These individuals, who once struggled with obesity and its associated health risks, have experienced life-changing results thanks to this groundbreaking medication.

Comparing Tirzepatide to Traditional Weight Loss Methods

When exploring weight loss options, understanding the differences between tirzepatide and traditional methods is crucial for making informed choices. This analysis will compare tirzepatide with conventional approaches, like diet and exercise, as well as other pharmaceutical interventions, to highlight its unique advantages and potential limitations.

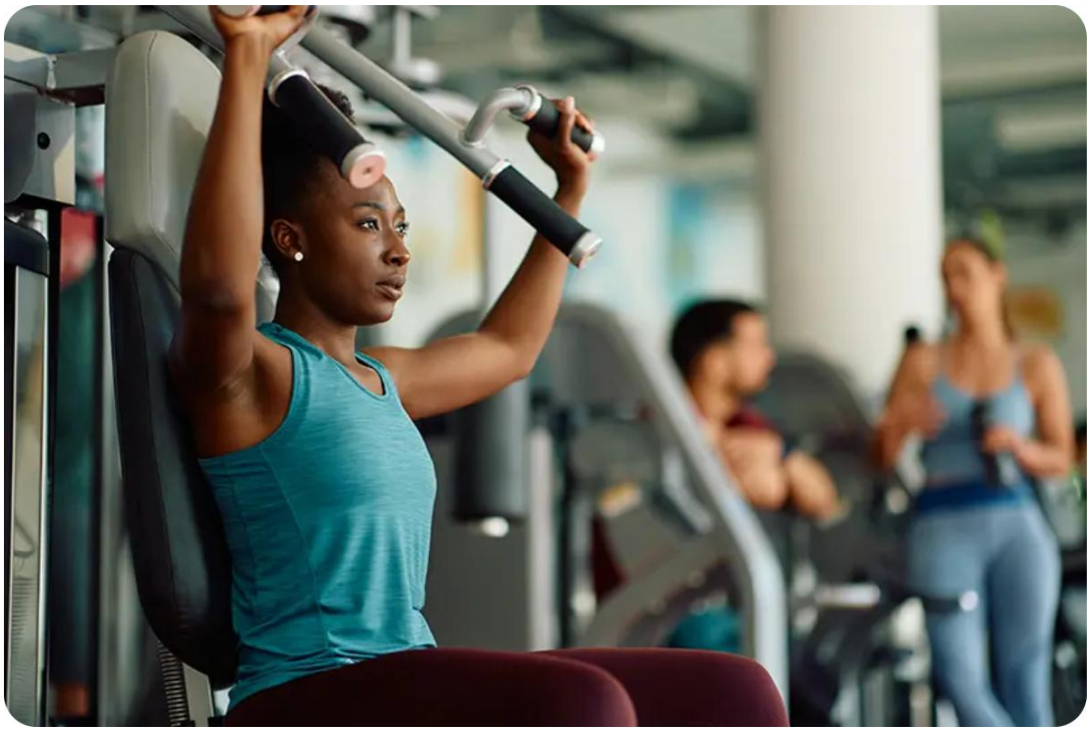
Diet and Exercise vs. Tirzepatide

Diet and exercise are classic approaches to weight loss, often viewed as the foundation for managing body weight. However, these methods can be challenging to maintain and sometimes yield modest results, especially for those with underlying metabolic issues. Tirzepatide, with its unique dual-action mechanism, offers a more targeted strategy for weight loss.

Traditional approaches require substantial lifestyle changes, such as calorie restriction and intense workouts. While these can be effective, they demand a high level of discipline and consistency. Tirzepatide, on the other hand, works by suppressing appetite and improving metabolic function, providing a significant boost to weight loss efforts without drastic dietary changes or rigorous exercise regimens.

Despite its potential, tirzepatide isn't a magic solution. It should be part of a holistic approach that includes healthy eating and regular physical activity. Here are some key points to consider:

- **Balanced Diet:** Tirzepatide can complement a nutrient-rich, calorie-controlled diet, helping to maintain satiety and reduce cravings.
- **Regular Exercise:** Physical activity supports metabolism and helps preserve lean muscle mass, which is crucial for sustained weight loss.
- **Long-Term Habits:** To ensure continued success, it's essential to develop sustainable habits that support a healthy lifestyle.



Tirzepatide vs. Other Pharmaceutical Interventions

In the realm of pharmaceutical weight loss interventions, tirzepatide stands out due to its dual-action targeting of both GLP-1 and GIP receptors. This unique approach gives it an edge over other medications that focus solely on one pathway, like semaglutide and liraglutide.

The dual-action mechanism allows tirzepatide to deliver superior weight loss outcomes. Clinical trials have shown that tirzepatide users often experience more significant weight loss compared to those using other medications. This is because the combination of GLP-1 and GIP activation creates a synergistic effect, leading to:

- **Enhanced Appetite Suppression:** Tirzepatide's ability to reduce hunger and control cravings is one of its most notable benefits.
- **Improved Metabolic Function:** By targeting both GLP-1 and GIP, tirzepatide helps to regulate insulin sensitivity and promote a healthier metabolism.
- **Greater Weight Loss:** Clinical studies indicate that tirzepatide users tend to achieve greater weight loss results compared to other pharmaceutical interventions.

Efficiency and Sustainability in Weight Loss Outcomes

When assessing weight loss methods, efficiency and sustainability are key factors to consider. Tirzepatide has gained recognition for its rapid and substantial weight reduction capabilities, with clinical trials indicating an average weight loss of 22.5% within 72 weeks of treatment. This level of

effectiveness is significantly higher than traditional lifestyle modifications and other weight loss medications. But who can benefit most from this groundbreaking medication?

Tirzepatide for Different Populations: Who Can Benefit?

Tirzepatide's unique approach to weight loss makes it a compelling option for a variety of populations. Whether you're dealing with obesity, managing diabetes, or facing other health issues, this medication might offer a path toward improved health and well-being.

Suitability for People with Obesity

Tirzepatide is designed to address the root causes of obesity by targeting the dual receptors GLP-1 and GIP. This approach makes it particularly suitable for individuals with a body mass index (BMI) of 30 or higher. By suppressing appetite and improving metabolic function, tirzepatide can help reduce food intake and support significant weight loss, offering hope to those struggling with obesity's challenges.

Implications for Diabetic Patients

For individuals with type 2 diabetes, tirzepatide can offer a dual benefit by aiding weight loss while also improving blood sugar control. The dual-action mechanism enhances insulin secretion and sensitivity, potentially allowing for better diabetes management. It's important to work closely with healthcare professionals when starting tirzepatide to monitor blood sugar levels and adjust other diabetes medications as needed.

Considerations for Other Health Conditions

Tirzepatide's weight loss benefits can positively impact other health conditions, such as cardiovascular disease, sleep apnea, and joint problems. By reducing body weight, tirzepatide can relieve strain on the heart, improve breathing during sleep, and alleviate pressure on joints. However, it's crucial to consult with your healthcare provider to ensure that tirzepatide is safe and appropriate for your specific health situation.

Health Condition	Potential Benefit of Tirzepatide
Cardiovascular Disease	Reduced strain on the heart
Sleep Apnea	Improved breathing during sleep
Joint Problems	Reduced pressure on joints

Potential Side Effects and Safety Concerns of Tirzepatide

If you're considering using tirzepatide for weight loss, it's crucial to be aware of its potential side effects and safety concerns. Although the medication has shown impressive results in clinical trials, understanding how it may affect you is vital to ensure a safe and effective experience.

By working closely with your healthcare provider and staying informed about common and less common side effects, you can navigate the use of tirzepatide with confidence, focusing on maximizing its benefits while minimizing risks.

Commonly Reported Side Effects

Like any medication, tirzepatide may cause side effects in some users. The most frequently reported adverse reactions are gastrointestinal in nature, with symptoms such as nausea, diarrhea, vomiting, constipation, and abdominal pain. These side effects are typically mild to moderate and tend to subside with continued use of the medication.

Additional potential side effects include injection site reactions, headache, fatigue, and dizziness. While less common, some users may also experience changes in appetite, indigestion, and flatulence. Here's a list of common and less common side effects:

Category	Side Effects
Common Side Effects	• Nausea • Diarrhea • Vomiting • Constipation • Abdominal pain
Less Common Side Effects	• Injection site reactions • Headache • Fatigue • Dizziness • Changes in appetite • Indigestion • Flatulence

Managing and Mitigating Side Effects

To manage and mitigate tirzepatide's potential side effects, a personalized approach is key. Work with your healthcare provider to develop a plan that reduces discomfort and ensures the medication's safe use. This could involve adjusting the dosage, taking tirzepatide with food, or implementing lifestyle changes to minimize adverse reactions.

In addition to guidance from your doctor, you can try the following self-care strategies to help manage side effects:

Side Effect	Management Strategy
Nausea	Eat smaller, more frequent meals and avoid fatty or spicy foods.
Diarrhea	Stay hydrated and consider over-the-counter antidiarrheal medication.
Constipation	Increase fiber intake, drink plenty of water, and exercise regularly.
Injection site reactions	Rotate injection sites and apply a cold compress to reduce swelling and discomfort.

By following these strategies and maintaining open communication with your healthcare team, you can ensure that the use of tirzepatide is both safe and effective. Remember, everyone's body responds differently to medication, so it's essential to monitor your symptoms and seek medical advice if you experience anything unusual or concerning.

The Importance of Open Communication with Your Healthcare Provider

When using tirzepatide for weight loss, maintaining open communication with your healthcare provider is crucial for a successful treatment journey. This dialogue is essential to ensure safety, manage side effects, and optimize the medication's effectiveness.

Regularly sharing your experiences, such as how you respond to tirzepatide and any side effects you encounter, allows your doctor to make informed adjustments to your treatment plan. It also helps build a strong partnership, where your healthcare provider is your guide, helping you navigate the complexities of using this medication.

Here's why open communication is critical:

- **Regular Feedback**: By sharing your progress and any concerns, your healthcare provider can offer tailored advice to address your specific needs.
- **Safety Measures**: Keeping your doctor informed about any unusual symptoms or side effects enables prompt intervention to mitigate risks.

enables prompt intervention to mitigate risks.

- **Effective Treatment**: Open communication ensures that you receive the best possible treatment, with adjustments made as needed to achieve optimal results.

Your healthcare provider is a key ally in your weight loss journey. Don't hesitate to ask questions or express concerns, as their expertise is vital for a safe and effective tirzepatide experience.

Professional Perspectives on Safety

Tirzepatide has undergone rigorous clinical trials, confirming its safety profile and efficacy in promoting weight loss. Medical professionals consider it generally well-tolerated, with most side effects being mild to moderate in severity and manageable with proper guidance. However, safety is paramount, and ongoing monitoring by your healthcare provider is essential to ensure the best outcomes.

Professional perspectives emphasize the following:

- **Medical Evaluation**: Before starting tirzepatide, undergo a comprehensive medical assessment to determine if the medication is suitable for you.
- **Adherence to Instructions**: Follow your healthcare provider's dosage recommendations and administration guidelines.
- **Regular Check-ups**: Regular visits to your healthcare provider allow for continuous monitoring and prompt attention to any emerging issues.
- **Reporting Symptoms**: If you experience unusual symptoms, promptly report them to your doctor to ensure swift action.

By following these safety guidelines and maintaining open communication with your healthcare provider, you can make the most of tirzepatide while minimizing risks.

The Future of Weight Loss: Tirzepatide's Role

Tirzepatide is poised to play a significant role in the future of obesity treatment. Its dual-action mechanism and strong clinical trial results suggest that it could revolutionize how we approach weight loss.

Emerging trends in obesity treatment focus on personalized approaches that consider the individual's metabolic profile and hormonal balance. Tirzepatide fits this approach, as it targets both GIP and GLP-1 receptors, offering a comprehensive solution to weight management. As research continues to explore the complex relationship between hormones, metabolism, and obesity, tirzepatide is expected to become a central player in future weight loss therapies.

Buy Tirzepatide

Moreover, experts predict that tirzepatide's success could lead to broader applications beyond weight loss. Its impact on metabolic disorders like type 2 diabetes, non-alcoholic fatty liver disease, and polycystic ovary syndrome could open new avenues for treatment. As tirzepatide gains wider recognition, its role in obesity management and related conditions could have a transformative effect on healthcare practices.

Leading experts in endocrinology and obesity medicine anticipate that tirzepatide will set a new standard in weight loss therapy, offering patients a more effective and sustainable path to achieving significant weight loss. As the medical community embraces its potential, tirzepatide could become a cornerstone in the future of weight loss and chronic disease management.

Tirzepatide Frequently Asked Questions

What is Tirzepatide? −

Tirzepatide is a groundbreaking medication tailored for weight management and blood sugar control, especially beneficial for individuals with obesity or Type 2 diabetes. It's unique as it combines the actions of GLP-1 and GIP receptors, amplifying its effectiveness in reducing appetite and enhancing insulin secretion, which in turn facilitates significant weight loss and improved glycemic control.

Is Tirzepatide the same as Mounjaro? +

How does Tirzepatide work for weight loss? +

How frequently should one administer Tirzepatide? +

Is compounded Tirzepatide safe? +

is compounded Tirzepatide safe?

What determines if I qualify for a Tirzepatide prescription? +

What is the difference between Semaglutide and Tirzepatide? +

Which is better, Semaglutide or Tirzepatide? +

Can I switch from Semaglutide to Tirzepatide? +

About HydraMed

HydraMed stands as a collective of medical professionals dedicated to pioneering advancements in longevity, smarter aging, and enabling individuals to lead fuller lives. Our unique approach disrupts traditional healthcare by offering innovative, accessible, and personalized health solutions. By empowering individuals to actively participate in their health and wellness journey, supported by the latest medical science and technology, we're making quality healthcare more convenient and tailored than ever. Our services include Anti-Aging RX treatments delivered directly to your doorstep and Mobile IV Therapy by Registered Nurses right to your home that is engineered for both preventive immune support and robust immune system strengthening, reflecting our commitment to accessibility and personalization in healthcare.

In the spirit of fostering a healthier, more vibrant future, HydraMed is guided by core values that prioritize safety, excellence, and innovation. Under the expert guidance of Dr. Thomas Paluska and Nurse Practitioner Courtney Williams, we ensure that all our treatments, especially our Anti-Aging RX home-kits, use only the highest quality compounds. These are meticulously crafted in the USA at FDA-registered pharmacies, underscoring our commitment to quality and safety. This dedication to using top-tier compounds and providing custom healthcare treatments reflects our mission to not just meet but exceed the healthcare needs of our community. By aligning our practices with these core values, HydraMed is not just a healthcare provider but a transformative force in the lives of those we serve, championing a future where everyone can live more, age smarter, and embrace life to its fullest.

Take Control of Weight Loss with Tirzepatide

Struggling with excess weight and seeking a solution that works? Discover the power of Tirzepatide for effective weight loss. This FDA-approved medication offers a convenient approach to shedding pounds, with a personalized program designed to meet your needs. With expert guidance and ongoing support, your journey to a healthier you is within reach. Start your weight loss transformation today with Tirzepatide and experience the benefits of a proven, personalized approach.

Learn More

Weight Loss Resources

- Weight Loss Wonders: 10 Methods That Shaped the History of Shedding Pounds
- What Is Semaglutide And How Is It Used For Weight Loss?
- B12 Shots for Weight Loss: What You Need to Know

Tirzepatide

- Tirzepatide Injections

HydraMed

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Written by Courtney Williams, FNP

Courtney Williams, a distinguished Nurse Practitioner with HydraMed, embodies our profound commitment to the principles of longevity, ensuring every treatment and consultation she provides is a step towards a fuller, healthier life. Her expertise is not merely in treating the present but in anticipating the future, guiding patients through hormone optimization, medical weight loss, and advanced peptide therapy with an eye on prolonging vitality and enhancing life quality.

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Medically Reviewed by Thomas Paluska, MD

Dr. Thomas Paluska, a proud veteran with an illustrious career spanning over 30 years in longevity and emergency medicine, is a cornerstone of HydraMed's commitment to pioneering health solutions. A distinguished Georgetown University graduate, Dr. Paluska honed his expertise through a rigorous emergency medicine residency at the Naval Medical Center, followed by a foundational transitional year internship at the National Capital Consortium.

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Tirzepatide | Injections | Peptide

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AO 120 (Rev. 08/10)

TO:	**Mail Stop 8** **Director of the U.S. Patent and Trademark Office** **P.O. Box 1450** **Alexandria, VA 22313-1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court District of Colorado on the following

☑ Trademarks or ☐ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	6/20/2024	District of Colorado

PLAINTIFF	DEFENDANT
ELI LILLY AND COMPANY	HydraMed IV LLC

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	6,809,369	8/2/2022	Eli Lilly and Company
2	7,068,463	5/30/2023	Eli Lilly and Company
3	7,288,373	1/23/2024	Eli Lilly and Company
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Colorado

Eli Lilly and Company

Plaintiff(s)

v.

HydraMed IV LLC

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* HydraMed IV LLC
11990 Grant Street, Suite 550
Northglenn, Colorado 80233

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Daniel N. Guisbond
WHEELER TRIGG O'DONNELL LLP
370 17th Street, Suite 4500
Denver, Colorado 80202-5647
Tel. (303) 244-1922
Fax (303) 244-1879

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

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Printed name and title

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Server's address

Additional information regarding attempted service, etc: