RonanRx
PERSONALIZED MEDICINE

CLINICAL MONOGRAPH · METABOLIC & WEIGHT

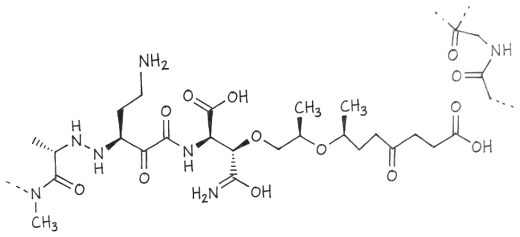
Compounded Semaglutide

GLP-1 receptor agonist for metabolic care

Semaglutide is a once-weekly injection (or once-daily pill) that lowers blood sugar and reduces appetite [fda_label_ozempic; fda_label_wegovy; wilding2021]. The brand-name versions are Ozempic and Rybelsus for type 2 diabetes, and Wegovy for chronic weight management. The FDA first approved it for diabetes in 2017 and for weight loss in 2021.

It works by mimicking a natural gut hormone called GLP-1. That hormone tells the pancreas to release insulin when blood sugar is high, slows how fast the stomach empties, and turns down hunger signals in the brain. In large clinical trials, people taking semaglutide for weight management lost about 15 percent of their starting body weight on average over a year.

RonanRx can prepare compounded semaglutide on a patient-specific prescription only when the FDA-approved manufactured product is not clinically appropriate for that patient. This is a doctor-prescribed therapy, not a direct-to-consumer product.



EVIDENCE POSTURE FDA APPROVED WELL STUDIED REVIEWED **2026-05-11**

State-licensed 503A | Pharmacist reviewed | Doctor led | Cold-chain ready | Patient choice preserved

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FOR CLINICIANS

Semaglutide is a 94 percent-homologous GLP-1 analogue with two structural modifications, an Aib-2 substitution that resists DPP-4 cleavage and a C18 fatty-diacid side chain that drives reversible albumin binding, yielding a circulating half-life of approximately one week and supporting once-weekly subcutaneous dosing [lau2015]. An oral tablet co-formulated with the absorption enhancer salcaprozate sodium (SNAC) achieves systemic exposure adequate for once-daily dosing.

FDA-approved indications span Ozempic (subcutaneous, type 2 diabetes, 2017; cardiovascular risk reduction in T2D with established CVD added subsequently), Rybelsus (oral, type 2 diabetes, 2019), and Wegovy (subcutaneous, chronic weight management in adults with BMI ≥30 or ≥27 with weight-related comorbidity, 2021; cardiovascular risk reduction in adults with obesity and established cardiovascular disease without diabetes added after the SELECT trial) [wilding2021; perkovic2024; fda_label_ozempic].

Evidence is anchored by the SUSTAIN trials (subcutaneous T2D), PIONEER trials (oral T2D), STEP trials (chronic weight management), SUSTAIN-6 and PIONEER 6 (cardiovascular outcomes in T2D), SELECT (cardiovascular outcomes in obesity without diabetes), FLOW (kidney outcomes in T2D plus CKD), and STEP-HFpEF (heart failure with preserved ejection fraction plus obesity) [lincoff2023; kosiborod2023]. Tolerability is dominated by dose-dependent gastrointestinal adverse events (nausea, vomiting, diarrhea, constipation). The labeled boxed warning concerns rodent thyroid C-cell tumors; contraindications include personal or family history of medullary thyroid carcinoma and MEN 2 [fda_shortage_resolution_2025] [drucker2018].

Compounded semaglutide is dispensed under 503A only with a documented patient-specific clinical reason that the manufactured product cannot meet (excipient sensitivity, a strength not commercially available, or another documented factor). Following the FDA's February 2025 declaratory order resolving the semaglutide shortage, the lawful basis for routine 503A compounding narrowed substantially [fda_label_wegovy; fda_label_rybelsus; smits2021].

Why Personalized Compounded Semaglutide

Semaglutide's FDA-approved dose was set by what worked acceptably across thousands of trial patients. It was not picked for your weight, your kidney function, your tolerance for nausea, or the other medications you take. Trial averages do not fit any one person exactly.

That gap is the work a compounding pharmacy does. A prescriber who knows your chart can start lower than the manufacturer's first dose, titrate slower if you have had GLP-1 side effects, or hold a step longer than the trial schedules used. The molecule is the same one the FDA reviewed. The dose and the cadence are yours.

This is what pharmacy looked like before mass manufacturing arrived. A doctor wrote the prescription. A pharmacist prepared it for that patient. Compounded semaglutide is that older arrangement, kept honest by modern oversight.

Quick Facts About Compounded Semaglutide

Category: Long-acting GLP-1 receptor agonist (glucagon-like peptide-1 analogue)

Class: Incretin mimetic; albumin-bound, DPP-4-resistant peptide engineered for once-weekly subcutaneous or once-daily oral dosing

FDA-approved branded products: Ozempic (subcutaneous, type 2 diabetes, 2017); Rybelsus (oral, type 2 diabetes, 2019); Wegovy (subcutaneous, chronic weight management, 2021; cardiovascular risk reduction in obesity without diabetes added after SELECT, 2024)

Routes studied in humans: Subcutaneous (once-weekly) and oral (once-daily tablet co-formulated with the absorption enhancer SNAC)

Evidence posture: Large randomized phase III evidence base for both diabetes (SUSTAIN, PIONEER) and weight management (STEP), plus cardiovascular outcomes (SUSTAIN-6, PIONEER 6, SELECT) and a dedicated kidney-outcomes trial (FLOW)

FDA-approval status: Manufactured Ozempic, Wegovy, and Rybelsus are FDA-approved. Compounded semaglutide preparations are not FDA-approved.

Compounded under: 503A, patient-specific prescription only, where the manufactured FDA-approved product is not clinically appropriate. The FDA-declared shortage of injectable semaglutide was resolved in February 2025, narrowing the lawful basis for routine compounding.

Important compounding caution: Per FDA guidance, compounded versions of an FDA-approved drug are generally restricted to documented patient-specific clinical need (allergy or sensitivity to a

manufactured-product excipient, a dose or strength not commercially available, or another clinical factor). Patient preference for a compounded product is not, on its own, a permissible basis.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Compounded Semaglutide described in this monograph is a 503A compounded preparation. Every dose is made on a prescription, for a named patient, by a licensed pharmacist. It is not a stocked, mass-manufactured product.

- **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
- **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
- **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
- **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
- **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

What is Compounded Semaglutide?

Semaglutide is a synthetic peptide analogue of human glucagon-like peptide-1 (GLP-1), a 30-amino-acid incretin hormone secreted by intestinal L-cells in response to nutrient intake [lau2015; drucker2018]. The molecule shares 94 percent sequence identity with native human GLP-1 and was engineered specifically for prolonged action and oral bioavailability.

Two structural changes underpin its pharmacology. First, the alpha-amino-isobutyric acid substitution at position 2 (Aib-2) prevents cleavage by dipeptidyl peptidase-4 (DPP-4), the enzyme that inactivates native GLP-1 within minutes. Second, a C18 fatty-diacid side chain attached at lysine-26 through a gamma-glutamic acid linker drives reversible binding to serum albumin. Albumin binding both extends the circulating half-life to approximately one week and reduces renal clearance of the peptide.

Three FDA-approved branded products are marketed in the United States: Ozempic (once-weekly subcutaneous injection for type 2 diabetes, first approved December 2017), Rybelsus (once-daily oral tablet for type 2 diabetes, approved September 2019, co-formulated with the permeation enhancer salcaprozate

sodium), and Wegovy (once-weekly subcutaneous injection for chronic weight management, approved June 2021) [fda_label_ozempic; fda_label_wegovy; fda_label_rybelsus].

How Compounded Semaglutide Works

Semaglutide is a long-acting agonist at the glucagon-like peptide-1 receptor (GLP-1R), a class B G-protein-coupled receptor expressed on pancreatic beta cells, alpha cells, gastric smooth muscle and enteric neurons, and several central nervous system populations including the hypothalamic arcuate nucleus, brainstem area postrema, and nodose ganglion [drucker2018; lau2015].

Activation of pancreatic beta-cell GLP-1R potentiates glucose-dependent insulin secretion: insulin release rises when plasma glucose is elevated and is unaffected at euglycemia, which is why GLP-1 receptor agonists carry low intrinsic hypoglycemia risk as monotherapy. GLP-1R activation on alpha cells suppresses glucagon secretion in a glucose-dependent manner.

Outside the pancreas, semaglutide slows gastric emptying, reduces appetite through central GLP-1R signaling in the hypothalamus and brainstem, and reduces food reward [smits2021]. These central effects are the primary driver of weight reduction in obesity and the major reason gastrointestinal side effects (nausea, vomiting, satiety) dominate the tolerability profile.

Biological Role of Compounded Semaglutide

Native GLP-1 is one of two principal incretin hormones (the other being glucose-dependent insulinotropic polypeptide, GIP) released from the gut in response to nutrient ingestion. It accounts for a substantial fraction of the insulin response to oral versus intravenous glucose loads in healthy humans, the so-called incretin effect, and that physiology is preserved or restorable in type 2 diabetes through pharmacological GLP-1R activation [husain2019].

Beyond glycemic regulation, GLP-1 signaling participates in central appetite regulation, gastric and intestinal motility, and a broad set of cardiometabolic processes whose mechanistic details continue to be characterized. The cardiovascular benefit observed across SUSTAIN-6, PIONEER 6, and SELECT is presumed to reflect a combination of weight loss, blood-pressure reduction, anti-inflammatory effects on the vasculature, and direct GLP-1R-mediated actions; isolating the contribution of each remains an active research question [marso2016; lincoff2023].

Semaglutide is a pharmacological tool whose footprint substantially exceeds native GLP-1 in both intensity (supra-physiologic receptor occupancy at therapeutic doses) and duration (week-long versus minutes). That difference is the source of both its therapeutic effect size and its characteristic adverse-event profile [drucker2018].

Detailed Mechanism of Compounded Semaglutide

GLP-1R is a class B (secretin-family) G-protein-coupled receptor signaling primarily through Gs-mediated activation of adenylate cyclase, with downstream cAMP-PKA and Epac2 effectors. In pancreatic beta cells, this signaling potentiates closure of ATP-sensitive K+ channels, depolarization, calcium influx, and exocytosis of insulin granules, but only when ambient glucose is already raising cytosolic ATP, which is the source of the agonist class's glucose-dependence [buckley2018stomachabsorption]. Alpha-cell GLP-1R activation suppresses glucagon in a glucose-dependent manner.

Semaglutide's near-week-long half-life reflects two engineered features. The Aib-2 substitution replaces the position-2 alanine that DPP-4 cleaves in native GLP-1 (which has a half-life of one to two minutes); semaglutide is essentially DPP-4-resistant [smits2021]. The C18 fatty-diacid acylation at Lys-26, attached through a hydrophilic gamma-glutamic acid spacer, provides high-affinity reversible binding to circulating albumin, which both extends plasma residence and protects against rapid renal filtration [lau2015; hall2018pk].

Oral semaglutide (Rybelsus) is co-formulated with the absorption enhancer salcaprozate sodium (SNAC). Mechanistic studies show SNAC transiently buffers gastric pH around the tablet and promotes transcellular absorption of the intact semaglutide peptide through the gastric epithelium, with absorption localized to a small region of stomach mucosa adjacent to the dissolving tablet [buckley2018stomachabsorption]. This is the basis for the strict empty-stomach, single-tablet, single-location absorption pattern of Rybelsus and for its narrow water and food timing requirements.

Centrally, GLP-1R-expressing neurons in the arcuate nucleus and area postrema integrate signals about satiety and meal context. Semaglutide signals through circumventricular organs and the area postrema to engage these populations, producing reductions in self-reported hunger, food craving, and energy intake that account for the bulk of the weight-loss effect observed in the STEP program. In adults with obesity, subcutaneous semaglutide 2.4 mg reduces energy intake at an ad libitum meal by approximately one-third and improves measures of eating control [friedrichsen2021appetite].

Slowed gastric emptying, most pronounced early in therapy and partially attenuated by tachyphylaxis with continued dosing, contributes to postprandial glucose lowering and to the dose-dependent gastrointestinal adverse-event profile (nausea, vomiting, early satiety). This pharmacology underlies perioperative recommendations to consider semaglutide hold timing in patients undergoing procedures that require an empty stomach; a retrospective endoscopy cohort showed substantially higher residual gastric content in patients on GLP-1 receptor agonists despite standard fasting [smits2021; overgaard2021oralpk; silveira2023perioperative].

The rodent thyroid C-cell tumor finding that drives the labeled boxed warning was characterized in non-clinical work showing that GLP-1 receptor activation in rodent thyroid C-cells produces calcitonin release and C-cell proliferation, with dose- and exposure-dependence; the clinical relevance of these findings in

humans, whose thyroid C-cells express GLP-1R at much lower density, remains unknown [drucker2018; bjerre2010thyroidrodent].

Compounded Semaglutide Research History

Glucagon-like peptide-1 was characterized as an incretin hormone in the 1980s, with subsequent work establishing the biology of the GLP-1 receptor and its potential as a therapeutic target [lau2015; drucker2018]. The first GLP-1 receptor agonist approved for type 2 diabetes, exenatide, reached the market in 2005, followed by liraglutide (a once-daily lipid-acylated analogue) in 2010 [capehorn2020sustain10; kosiborod2024stephfpefdm]. Both established the class as efficacious for glycemic control with weight loss as a consistent secondary effect.

Semaglutide was designed at Novo Nordisk explicitly to extend the half-life beyond liraglutide's daily window by increasing albumin binding affinity [rubino2022step8]. Lau and colleagues published the discovery and preclinical characterization in 2015, describing the Aib-2 substitution and the C18 fatty-diacid acylation that together produce the once-weekly profile in humans.

Clinical development proceeded along three parallel tracks. The SUSTAIN program (SUSTAIN 1 through 10) established efficacy and safety of once-weekly subcutaneous semaglutide across the type 2 diabetes treatment cascade against placebo and a range of active comparators including sitagliptin in SUSTAIN 2, exenatide ER, insulin glargine, dulaglutide in SUSTAIN 7, an SGLT2-inhibitor as add-on, and once-daily liraglutide in SUSTAIN 10 [sorli2017; ahren2017; aroda2019]. SUSTAIN-6, the dedicated cardiovascular outcomes trial in patients with T2D and high CV risk, demonstrated a reduction in major adverse cardiovascular events with semaglutide versus placebo [marso2016]. The PIONEER program then validated the oral SNAC-co-formulated tablet (Rybelsus) across the same treatment cascade in PIONEER 1 and against active comparators in PIONEER 2 through 8, including subcutaneous liraglutide in PIONEER 4 and moderate renal impairment in PIONEER 5, with PIONEER 6 establishing cardiovascular safety [husain2019; mosenzon2019pioneer5] [pratley2019pioneer4]. Higher oral doses (25 mg and 50 mg) were subsequently evaluated in PIONEER PLUS. A pooled phase IIIa safety report covering the combined SUSTAIN and PIONEER programs documented the gastrointestinal-dominated tolerability profile across approximately 19,000 randomized participants [aroda2023safetypooled] [sanyal2025essence].

The STEP program extended development into chronic weight management. STEP 1 demonstrated approximately 15 percent mean weight loss at 68 weeks in adults with overweight or obesity without diabetes; STEP 2 evaluated the same in adults with T2D; STEP 3 paired semaglutide with intensive behavioral therapy; STEP 4 examined weight-loss maintenance with a randomized-withdrawal design; STEP 5 demonstrated two-year durability; STEP 8 compared semaglutide 2.4 mg weekly to liraglutide 3.0 mg daily and reported greater weight loss with semaglutide; STEP TEENS extended the indication to adolescents [pratley2018sustain7; aroda2023pioneerplus; wilding2021]. The STEP 1 extension trial documented substantial weight regain after semaglutide withdrawal, framing therapy as long-term rather

than time-limited [wilding2022step1ext] [wadden2021; garvey2022]. The SELECT trial [lincoff2023] randomized adults with obesity and established cardiovascular disease but without diabetes and reported a 20 percent relative reduction in major adverse cardiovascular events, supporting an additional cardiovascular risk-reduction indication [colhoun2024selectkidney] [rubino2021]. A pre-specified SELECT sub-analysis subsequently demonstrated reduction in kidney composite outcomes.

Subsequent trials have extended evidence into heart failure with preserved ejection fraction in obesity (STEP-HFpEF and STEP-HFpEF DM in patients with concomitant type 2 diabetes), chronic kidney disease in type 2 diabetes (FLOW), metabolic dysfunction-associated steatohepatitis (the Newsome 2021 phase 2 trial and the phase 3 ESSENCE trial reported by Sanyal and colleagues in 2025), and knee osteoarthritis in adults with obesity [davies2021step2; kosiborod2023; perkovic2024]. Higher-dose oral semaglutide was evaluated for obesity in OASIS 1 (50 mg once daily) [knop20230asis1] [weghuber2022; bliddal2024osteoarthritis]. Systematic reviews, network meta-analyses, and direct and indirect comparisons against tirzepatide are accumulating and consistently rank semaglutide in the upper tier of the GLP-1 receptor agonist class [lee2025cvkidneymeta; rodriguez2024semavstirz] [newsome2021].

Compounded Semaglutide Timeline

1980s • GLP-1 characterized as an incretin hormone; receptor biology elaborated through the 1990s

2005 • Exenatide (the first GLP-1 receptor agonist) FDA-approved for type 2 diabetes, establishes the class clinically

2010 • Liraglutide (once-daily acylated GLP-1 analogue) FDA-approved for type 2 diabetes; later (2014) approved for chronic weight management as Saxenda

2015 • Lau et al [lau2015]. publish the discovery and preclinical characterization of semaglutide, describing the Aib-2 substitution and C18 fatty-diacid acylation that produce its once-weekly profile

2016 • SUSTAIN-6 cardiovascular outcomes trial published, semaglutide reduces major adverse cardiovascular events in adults with T2D and high CV risk [marso2016]

2017 • SUSTAIN 1 and SUSTAIN 2 published, establishing once-weekly semaglutide as monotherapy and add-on therapy in T2D [sorli2017; ahren2017]

2017 • FDA approves Ozempic (semaglutide subcutaneous injection) for type 2 diabetes [fda_label_ozempic]

2018 • Drucker publishes comprehensive Cell Metabolism review of GLP-1 receptor biology and therapeutic application [drucker2018]

2019 • PIONEER 1 demonstrates efficacy of oral semaglutide monotherapy in T2D; PIONEER 6 establishes cardiovascular safety of oral semaglutide [aroda2019; husain2019]

2019 • FDA approves Rybelsus (oral semaglutide tablets co-formulated with SNAC) for type 2 diabetes, the first oral GLP-1 receptor agonist [fda_label_rybelsus]

2021 • STEP 1 published, approximately 15 percent mean weight loss at 68 weeks in adults with overweight or obesity without diabetes [wilding2021]

2021 • STEP 2, STEP 3, and STEP 4 published, efficacy in T2D-plus-obesity, as adjunct to intensive behavioral therapy, and weight-loss maintenance [davies2021step2; wadden2021; rubino2021]

2021 • FDA approves Wegovy (semaglutide 2.4 mg subcutaneous) for chronic weight management in adults [fda_label_wegovy]

2021 • Newsome et al [newsome2021]. publish phase 2 trial of subcutaneous semaglutide in non-alcoholic steatohepatitis (NASH), showing significantly higher NASH-resolution rates

2021 • Smits and Van Raalte publish comprehensive safety review of semaglutide across diabetes and weight-management indications [smits2021]

2022 • STEP 5 demonstrates durability of semaglutide weight loss to two years; STEP TEENS extends evidence to adolescents [garvey2022; weghuber2022]

2023 • SELECT trial published, semaglutide reduces major adverse cardiovascular events by 20 percent in adults with obesity and established CVD but without diabetes [lincoff2023]

2023 • STEP-HFpEF demonstrates symptom and functional improvement in heart failure with preserved ejection fraction plus obesity [kosiborod2023]

2024 • FLOW trial published, semaglutide reduces kidney-related and cardiovascular death events in T2D plus chronic kidney disease [perkovic2024]

2024 • FDA expands Wegovy label to include cardiovascular risk reduction in adults with obesity and established cardiovascular disease without diabetes, based on SELECT [fda_label_wegovy; lincoff2023]

2025 • FDA issues declaratory order resolving the semaglutide injection shortage (February 2025), and subsequent guidance establishing enforcement deadlines for 503A and 503B compounders to wind down routine semaglutide compounding [fda_shortage_resolution_2025]

Clinical Contexts for Compounded Semaglutide

Type 2 diabetes mellitus, once-weekly subcutaneous FDA APPROVED

> Semaglutide treats type 2 diabetes. It's a once-weekly injection at 0.5, 2 mg.

FDA-approved indication for the manufactured Ozempic product.

Ozempic is FDA-approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes, and to reduce the risk of major adverse cardiovascular events in adults with T2D and established cardiovascular disease [fda_label_ozempic; marso2016]. SUSTAIN-1 [sorli2017] demonstrated mean HbA1c reductions of approximately 1.5 percentage points with 0.5 mg and 1.6 percentage points with 1.0 mg versus placebo at 30 weeks. SUSTAIN-2 [ahren2017] replicated superiority versus sitagliptin.

Branded product: Ozempic (semaglutide injection, Novo Nordisk)

Type 2 diabetes mellitus, once-daily oral FDA APPROVED

> Semaglutide is also FDA-approved as an oral once-daily pill (Rybelsus) for type 2 diabetes, at 7 mg or 14 mg.

FDA-approved indication for the manufactured Rybelsus product.

Rybelsus is FDA-approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. PIONEER 1 [aroda2019] randomized 703 patients to oral semaglutide 3, 7, or 14 mg or placebo over 26 weeks and demonstrated dose-dependent HbA1c and body-weight reductions versus placebo [fda_label_rybelsus]. PIONEER 6 [husain2019] established cardiovascular safety (noninferiority) in 3183 patients at high CV risk over a median 15.9 months.

Branded product: Rybelsus (semaglutide tablets, Novo Nordisk)

Chronic weight management in adults with obesity or overweight plus comorbidity

FDA APPROVED

> Semaglutide 2.4 mg weekly is FDA-approved for chronic weight management in adults with obesity, or overweight plus a weight-related condition.

FDA-approved indication for the manufactured Wegovy product.

Wegovy is FDA-approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with BMI ≥30 kg/m², or ≥27 kg/m² with at least one weight-related comorbidity. STEP 1 [wilding2021] randomized 1961 adults without diabetes to subcutaneous semaglutide 2.4 mg or placebo for 68 weeks and reported a mean body-weight change of −14.9 percent versus −2.4 percent with placebo. STEP 4 [rubino2021] demonstrated that continued semaglutide maintained weight loss whereas placebo led to regain [fda_label_wegovy]. STEP 5 [garvey2022] extended durability to 104 weeks.

Branded product: Wegovy (semaglutide 2.4 mg injection, Novo Nordisk)

Cardiovascular risk reduction in adults with established cardiovascular disease and obesity, without diabetes

FDA APPROVED

FDA-approved indication added to Wegovy labeling following SELECT.

The SELECT trial [lincoff2023] randomized 17,604 adults aged 45 or older with preexisting cardiovascular disease and BMI ≥27 but without diabetes to subcutaneous semaglutide 2.4 mg or placebo, with a median follow-up of 39.8 months. The primary composite endpoint (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) occurred in 6.5 percent of the semaglutide group versus 8.0 percent of the placebo group (hazard ratio 0.80; 95% CI 0.72, 0.90; P<0.001) [fda_label_wegovy].

Branded product: Wegovy

Cardiovascular risk reduction in adults with type 2 diabetes and established cardiovascular disease

FDA APPROVED

FDA-approved indication for Ozempic; supported by SUSTAIN-6.

SUSTAIN-6 [marso2016] randomized 3297 patients with type 2 diabetes at high cardiovascular risk to once-weekly subcutaneous semaglutide or placebo over 104 weeks [fda_label_ozempic]. The primary composite outcome occurred in 6.6 percent of semaglutide-treated patients versus 8.9 percent on placebo (hazard ratio 0.74; 95% CI 0.58, 0.95).

Branded product: Ozempic

Type 2 diabetes with overweight or obesity WELL STUDIED

Studied in dedicated phase III trials; aligns with both diabetes and weight-management label populations.

STEP 2 [davies2021step2] randomized 1210 adults with T2D and overweight or obesity to subcutaneous semaglutide 2.4 mg, 1.0 mg, or placebo over 68 weeks. The 2.4 mg arm achieved a mean body-weight change of −9.6 percent versus −3.4 percent with placebo and significantly greater HbA1c reduction. The trial supports the use of higher-dose semaglutide for combined metabolic and weight outcomes in T2D.

Chronic weight management as adjunct to intensive behavioral therapy WELL STUDIED

Evaluated in a dedicated phase III trial; consistent with FDA-label adjunctive framing.

STEP 3 [wadden2021] randomized 611 adults with overweight or obesity to subcutaneous semaglutide 2.4 mg or placebo, both with intensive behavioral therapy, over 68 weeks. The semaglutide arm achieved a mean body-weight change of −16.0 percent versus −5.7 percent with placebo, with 86.6 percent versus 47.6 percent of participants achieving at least 5 percent weight loss.

Chronic kidney disease in adults with type 2 diabetes WELL STUDIED

Dedicated phase III outcomes trial; not currently an FDA-approved indication for compounded preparations.

FLOW [perkovic2024] randomized 3533 patients with type 2 diabetes and chronic kidney disease to subcutaneous semaglutide 1.0 mg weekly or placebo. The primary composite kidney outcome (kidney failure, sustained ≥50 percent reduction in eGFR, or kidney or cardiovascular death) occurred in 24 percent fewer participants on semaglutide (hazard ratio 0.76; 95% CI 0.66, 0.88).

Heart failure with preserved ejection fraction in adults with obesity WELL STUDIED

Dedicated phase III trial; supports symptom and functional benefit in this population. Replicated in patients with concomitant type 2 diabetes.

STEP-HFpEF [kosiborod2023] randomized 529 participants with symptomatic HFpEF, ejection fraction ≥45 percent, and BMI ≥30 to subcutaneous semaglutide 2.4 mg or placebo over 52 weeks. The semaglutide arm achieved greater improvement in the Kansas City Cardiomyopathy Questionnaire clinical summary score and greater weight loss, with improvements in six-minute walk distance and C-reactive protein. STEP-HFpEF DM [kosiborod2024stephfpefdm] replicated the symptomatic and weight benefits in 616 participants with HFpEF, obesity, and type 2 diabetes.

Metabolic dysfunction-associated steatohepatitis (MASH) with fibrosis EMERGING

Phase 3 evidence published 2025; no FDA-approved semaglutide MASH indication at time of writing.

The phase 3 ESSENCE trial [sanyal2025essence] randomized adults with biopsy-confirmed MASH and stage F2 or F3 fibrosis to subcutaneous semaglutide 2.4 mg weekly or placebo, with prespecified histologic endpoints at 72 weeks [newsome2021]. Semaglutide produced significantly higher rates of MASH resolution without worsening of fibrosis and of fibrosis improvement without worsening of MASH versus placebo. Earlier phase 2 evidence from Newsome and colleagues (2021) had demonstrated MASH resolution but not fibrosis improvement at 72 weeks.

Knee osteoarthritis in adults with obesity EMERGING

Dedicated phase 3 trial in obesity-associated knee osteoarthritis; not an FDA-approved indication.

Bliddal 2024 (NEJM) randomized 407 adults with obesity and clinically significant knee osteoarthritis pain to subcutaneous semaglutide 2.4 mg or placebo for 68 weeks [bliddal2024osteoarthritis]. Semaglutide produced greater weight loss and greater reductions in WOMAC pain scores versus placebo, supporting weight reduction as a treatment lever for obesity-associated osteoarthritis pain.

Comparative efficacy versus tirzepatide for weight loss WELL STUDIED

Direct randomized and real-world comparisons; not an FDA-approved indication. Informs choice between class agents.

Real-world cohort data [rodriguez2024semavstirz] and direct randomized comparisons consistently show greater weight loss with tirzepatide than semaglutide at the highest labeled doses of each. Pooled and systematic comparisons place tirzepatide above semaglutide for weight-loss efficacy, with overlapping but generally similar tolerability profiles dominated by gastrointestinal events.

Pediatric and adolescent obesity (ages 12 to <18) FDA APPROVED

FDA-approved indication for Wegovy in adolescents; supported by STEP TEENS.

STEP TEENS [weghuber2022] randomized 201 adolescents aged 12 to less than 18 years with obesity or overweight plus a weight-related comorbidity to subcutaneous semaglutide 2.4 mg or placebo for 68 weeks. Mean BMI change was −16.1 percent with semaglutide versus +0.6 percent with placebo, supporting the FDA-approved Wegovy indication in adolescents 12 and older [fda_label_wegovy].

Branded product: Wegovy

Off-Label Uses of Compounded Semaglutide

Metabolic dysfunction-associated steatohepatitis (MASH / NASH) EMERGING

Phase 3 ESSENCE trial published 2025; no FDA-approved semaglutide indication at time of writing.

Newsome 2021 randomized 320 patients with biopsy-confirmed NASH and fibrosis stage F1, F3 to once-daily subcutaneous semaglutide 0.1, 0.2, or 0.4 mg or placebo over 72 weeks [newsome2021]. The 0.4 mg arm achieved NASH resolution in 59 percent of participants versus 17 percent with placebo, although the trial did not demonstrate a significant difference in fibrosis improvement. The subsequent phase 3 ESSENCE trial [sanyal2025essence] reported significantly higher rates of MASH resolution without worsening of fibrosis and of fibrosis improvement without worsening of MASH with semaglutide 2.4 mg versus placebo in adults with biopsy-confirmed MASH and stage F2 or F3 fibrosis at 72 weeks.

Cardiovascular risk reduction outside SELECT and SUSTAIN-6 populations EMERGING

Used off-label in cardiometabolic practice; class-level rationale extrapolated from major outcomes trials.

Some clinicians extrapolate cardiovascular benefit to patients outside the precise inclusion criteria of SELECT (obesity plus established CVD, no diabetes), SUSTAIN-6, or PIONEER 6 [lincoff2023; marso2016; husain2019]. Such use is off-label; effect sizes in unstudied populations are not established and should be discussed as such.

FDA-Approved Uses of Compounded Semaglutide

Brand	Indication	Year	Route
Ozempic	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes; reduction of major adverse cardiovascular events in adults with T2D and established cardiovascular disease	2017	Subcutaneous, once-weekly injection (0.25, 0.5, 1.0, and 2.0 mg pens)
Rybelsus	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes	2019	Oral tablet, once daily (3, 7, 14 mg)
Wegovy	Chronic weight management in adults with BMI ≥30 kg/m² or ≥27 kg/m² with at least one weight-related comorbidity; adolescents 12 years and older with obesity; reduction of major adverse cardiovascular events in adults with obesity and established cardiovascular disease without diabetes (added after SELECT)	2021	Subcutaneous, once-weekly injection (titrated to 2.4 mg)

Three FDA-approved branded products carry semaglutide. Ozempic was first approved in December 2017 for type 2 diabetes; its label was subsequently expanded to include reduction of major adverse cardiovascular events in adults with T2D and established cardiovascular disease [fda_label_ozempic]. Rybelsus was approved in September 2019 as the first oral GLP-1 receptor agonist, using salcaprozate sodium (SNAC) as a permeation enhancer [fda_label_rybelsus]. Wegovy was approved in June 2021 for chronic weight management; its indication was expanded after the SELECT trial to include cardiovascular risk reduction in adults with obesity and established cardiovascular disease without diabetes, and a separate adolescent indication followed STEP TEENS [fda_label_wegovy; lincoff2023; weghuber2022].

All three carry a boxed warning regarding rodent thyroid C-cell tumors and a contraindication in patients with a personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) [fda_label_ozempic]. Common adverse events across the labels are dominated by gastrointestinal effects (nausea, vomiting, diarrhea, constipation), and labels include warnings on pancreatitis, gallbladder disease, hypoglycemia when used with insulin or sulfonylureas, acute kidney injury (often secondary to volume depletion from gastrointestinal events), retinopathy complications in T2D, and hypersensitivity.

Compounded Compounded Semaglutide (503A)

Compounded semaglutide is dispensed under 503A only when the prescribing clinician documents a patient-specific clinical need that the FDA-approved manufactured products (Ozempic, Wegovy, or Rybelsus) cannot meet. Acceptable bases include documented sensitivity to an excipient in the manufactured product, a strength or formulation not commercially available, or another individualized clinical factor recorded in the prescription. Patient preference for a compounded product is not, on its own, a permissible basis under FDA guidance [fda_essentially_a_copy].

The regulatory landscape changed materially in 2025. The FDA issued a declaratory order resolving the semaglutide injection shortage in February 2025, and subsequent guidance established enforcement deadlines for 503A and 503B compounders to wind down routine semaglutide compounding tied to the prior shortage. After those deadlines, the only lawful basis for compounding remains the documented patient-specific clinical need described above; routine substitution of compounded semaglutide for the manufactured product is restricted [fda503a].

RonanRx's pharmacist review evaluates each prescription against this criterion before dispensing. RonanRx does not fill prescriptions for compounded semaglutide that read as routine substitution for an FDA-approved branded product without a documented clinical reason. The FDA has separately documented adverse-event reports associated with compounded semaglutide products, including dosing errors in patients self-administering from multi-dose vials, reinforcing the need for clinical supervision [fda_shortage_resolution_2025; fda_compounding_risk_alert].

Compounded Semaglutide Formulations and Routes

Form	Concentration	Description
Compounded subcutaneous injection (semaglutide acetate or semaglutide sodium in a sterile aqueous vehicle)	Custom, typically expressed in mg/mL; per-patient strength determined by the prescribing clinician based on clinical need	Sterile compounded preparation prepared under USP <797> sterile compounding standards on a patient-specific prescription. Not bioequivalent to manufactured Ozempic or Wegovy; bioavailability and PK from a compounded vial differ from a pre-filled manufactured pen.

Routes used in published literature: subcutaneous, oral.

Compounded Semaglutide Dosing

Route	Population	Range	Duration	Study type
Subcutaneous	Adults with type 2 diabetes (Ozempic label population)	0.25 mg once weekly for 4 weeks (initiation), then 0.5 mg once weekly; may titrate to 1.0 mg weekly after at least 4 weeks if additional glycemic control is needed; maximum 2.0 mg once weekly	Indefinite while clinically beneficial	FDA-approved labeled regimen
Subcutaneous	Adults with overweight or obesity (Wegovy label population)	Titration schedule: 0.25 mg weekly for 4 weeks, then 0.5 mg, 1.0 mg, 1.7 mg, and finally 2.4 mg weekly, each step held for 4 weeks; maintenance 2.4 mg once weekly	Indefinite while clinically beneficial; reassess weight-loss response per label criteria	FDA-approved labeled regimen
Subcutaneous	Adolescents 12 years and older with obesity (Wegovy label population)	Same titration schedule as adults to a maintenance dose of 2.4 mg once weekly; tolerability-driven down-titration to a maximum tolerated dose is permitted	Indefinite while clinically beneficial	FDA-approved labeled regimen; supported by STEP TEENS
Oral	Adults with type 2 diabetes (Rybelsus label population)	3 mg once daily for 30 days (initiation), then 7 mg once daily; may increase to 14 mg once daily after at least 30 days if additional glycemic control is needed;	Indefinite while clinically beneficial	FDA-approved labeled regimen

Route	Population	Range	Duration	Study type
		tablets must be taken on an empty stomach with up to 4 oz of plain water at least 30 minutes before the first food, beverage, or other oral medication of the day		
Subcutaneous	Adults with T2D plus chronic kidney disease (clinical trial dose)	1.0 mg once weekly was the dose evaluated in the FLOW outcomes trial; not currently a separate label	Median follow-up 3.4 years in FLOW	Phase III outcomes trial

Titration pacing is the primary tolerability lever for semaglutide [smits2021]. Gastrointestinal adverse events (nausea, vomiting, diarrhea, constipation) concentrate in the first weeks of each dose step and are the dominant cause of discontinuation across the SUSTAIN, PIONEER, and STEP programs. The label-defined four-week-per-step titration balances time-to-target dose against tolerability; slower titration is acceptable when an individual patient requires it.

Compounded preparations should not be prescribed above the maximum labeled dose for the relevant indication (2.0 mg weekly for type 2 diabetes; 2.4 mg weekly for chronic weight management; 14 mg daily oral for type 2 diabetes). Higher doses have not been studied in pivotal trials, and adverse-event reports associated with compounded preparations have included consequences of dosing errors that exceeded the labeled range [fda_compounding_risk_alert].

Patients with insulin or sulfonylurea co-therapy should have those agents reviewed for dose reduction at semaglutide initiation, given the increased risk of hypoglycemia [fda_label_ozempic; fda_label_wegovy; fda_compounding_risk_alert]. Patients undergoing procedures requiring an empty stomach should follow current society guidance regarding GLP-1 receptor agonist hold timing because of delayed gastric emptying.

Compounded Semaglutide Safety

The safety profile of semaglutide is dominated by gastrointestinal adverse events and is consistent across the SUSTAIN, PIONEER, and STEP programs [18][31][52]. The most common adverse events are nausea (approximately 20, 44 percent depending on dose and indication), vomiting, diarrhea, and constipation; these are mostly mild to moderate, concentrated in the titration period, and the leading cause of discontinuation across trials [8][31].

Labeled boxed warnings and class warnings include rodent thyroid C-cell tumors (proliferative response demonstrated in rodents; clinical relevance to humans remains unknown, and a published systematic review and meta-analysis of randomized trials did not detect a thyroid- or overall-cancer signal in patients receiving semaglutide), pancreatitis (signal small and inconsistent across meta-analyses), gallbladder

disease and cholelithiasis (consistently elevated with rapid weight loss), acute kidney injury (often secondary to volume depletion from GI events), retinopathy complications in patients with type 2 diabetes (observed in SUSTAIN-6 and analyzed by Vilsbøll and colleagues as concentrated in patients with pre-existing retinopathy and rapid HbA1c reduction), hypersensitivity reactions, and hypoglycemia when used in combination with insulin or sulfonylureas [34454].

Psychiatric safety has been examined in both trial post-hoc analyses and pharmacovigilance datasets. A post-hoc analysis of STEP 1, 2, 3, and 5 found no increase in depression or suicidal ideation versus placebo in participants without known major psychopathology [51]. Pharmacovigilance signals from EudraVigilance and WHO Vigibase have flagged spontaneous reports of depression, anxiety, and suicidal ideation across the GLP-1 receptor agonist class that warrant ongoing monitoring.

Compounded preparations carry additional risks tied to sourcing, sterility, and dosing accuracy. The FDA has received hundreds of adverse-event reports associated with compounded semaglutide and tirzepatide, with dosing errors from patient self-administration of multi-dose vials a recurring theme [192025]. A FAERS pharmacovigilance analysis specific to compounded GLP-1 receptor agonists characterized the reported events as predominantly dosing-related and gastrointestinal, and a population-level analysis documented a rise in accidental-overdose reports concurrent with the expansion of compounded GLP-1 use [5556]. These are not pharmacological properties of the molecule itself but reflect the practical realities of compounded versus manufactured pre-filled-pen preparations [5345].

Contraindications

Semaglutide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), in patients with a prior serious hypersensitivity reaction to semaglutide or any of the product excipients, and (per the Wegovy and Ozempic labels) in pregnancy because of potential fetal harm from weight loss and from the medication itself [192021].

Caution and clinical judgment are required in patients with a history of pancreatitis (signal is small but the labels carry a warning), severe gastroparesis or other significant pre-existing gastrointestinal dysmotility, active diabetic retinopathy with high-risk features, or active gallbladder disease.

Drug interactions

Semaglutide delays gastric emptying, which can in principle slow the absorption of co-administered oral medications. Clinically significant interactions with most oral agents have not been demonstrated, but oral medications with narrow therapeutic indices warrant attention.

Combination with insulin or insulin secretagogues (sulfonylureas, meglitinides) increases the risk of hypoglycemia; dose reduction of the concomitant agent at semaglutide initiation is standard practice.

Oral semaglutide (Rybelsus) interacts pharmacokinetically with the SNAC absorption enhancer in the tablet. The tablet must be taken on an empty stomach with up to 4 oz of plain water at least 30 minutes

before the first food, beverage, or other oral medication of the day; co-ingestion materially reduces semaglutide absorption [19][21][18].

Adverse events

Across the STEP program (Wegovy 2.4 mg, combined N approximately 4500), the most common adverse events with semaglutide versus placebo were nausea (approximately 44 percent vs 17 percent in STEP 1), diarrhea (approximately 32 percent vs 16 percent), vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, and abdominal distension [8]. Discontinuation due to gastrointestinal events occurred in approximately 4, 7 percent of semaglutide-treated participants across trials, versus roughly 1, 3 percent on placebo. A pooled phase IIIa safety report across the SUSTAIN and PIONEER programs replicates this profile in type 2 diabetes populations [31].

In SUSTAIN-6 [3], retinopathy complications occurred more often with semaglutide than placebo (3.0 percent vs 1.8 percent); a dedicated post-hoc analysis demonstrated that this signal was concentrated in patients with pre-existing retinopathy and rapid HbA1c reduction, consistent with the broader 'early worsening' phenomenon described with rapid glycemic improvement [45]. Pancreatitis rates were numerically similar across active and placebo arms in SUSTAIN-6, PIONEER 6, and SELECT; an updated meta-analysis across semaglutide regimens did not identify a statistically significant increase in acute pancreatitis [53]. A meta-analysis of cancer outcomes across semaglutide randomized trials did not identify a thyroid- or overall-cancer signal [14][54].

FDA has received hundreds of adverse-event reports associated with compounded semaglutide products, many involving dosing errors and some requiring hospitalization [25][18]. A pharmacovigilance analysis of FAERS reports specific to compounded GLP-1 receptor agonists characterized the reported events as dominated by dosing errors and gastrointestinal events [55]. These are not properties of the molecule but reflect the practical risks of multi-dose vial self-administration when compared to manufactured pre-filled pens with built-in dose-step mechanisms.

Psychiatric adverse events have been examined in both prospectively collected trial data and pharmacovigilance datasets [52]. A pooled post-hoc analysis of STEP 1, 2, 3, and 5 found no increase in depression, anxiety, or suicidal ideation versus placebo in participants without known major psychopathology; pharmacovigilance signals from EudraVigilance continue to be assessed [51].

Monitoring Compounded Semaglutide Therapy

Baseline assessment for a patient starting semaglutide should include weight, blood pressure, heart rate, HbA1c when relevant, an estimate of renal function, a history for personal or family medullary thyroid carcinoma or MEN 2, a history for pancreatitis, gallbladder symptoms, eating disorder symptoms, and pregnancy status [fda_label_ozempic]. In patients with type 2 diabetes, dilated retinal examination at

baseline and per current diabetic retinopathy screening guidance is appropriate, given the SUSTAIN-6 retinopathy signal [marso2016].

On therapy, monitoring follows the relevant indication: weight, blood pressure, and tolerability for chronic weight management; HbA1c, weight, and tolerability for type 2 diabetes; renal function periodically and when symptomatic volume depletion occurs. Reassessment of insulin or sulfonylurea co-therapy at each dose increase is appropriate.

Per the Wegovy label, response should be reassessed periodically; clinical society guidance generally recommends evaluating whether at least 5 percent body-weight reduction has been achieved by approximately 12 weeks at the maintenance dose, with continuation or discontinuation decisions individualized [fda_label_wegovy].

Compounded Semaglutide in Special Populations

Compounded Semaglutide Evidence Quality

The evidence base for manufactured semaglutide is among the strongest for any cardiometabolic medication in the modern era [mosenzon2019pioneer5; aroda2023pioneerplus; wilding2022step1ext]. The SUSTAIN program (10+ phase III randomized trials in type 2 diabetes against placebo and active comparators including sitagliptin, dulaglutide, and liraglutide), the PIONEER program (10 randomized trials of oral semaglutide including PIONEER 4 versus subcutaneous liraglutide, PIONEER 5 in renal impairment, the cardiovascular-safety PIONEER 6, and higher doses in PIONEER PLUS), and the STEP program in chronic weight management (spanning adults, T2D plus obesity, behavioral-therapy adjuncts, weight-loss maintenance, two-year durability, adolescents, head-to-head against liraglutide, and a withdrawal extension) together represent tens of thousands of randomized participants with consistent efficacy signals across populations and outcomes [sorli2017; ahren2017; marso2016]. Cardiovascular and kidney outcomes are anchored by SUSTAIN-6, PIONEER 6, SELECT with a pre-specified kidney sub-analysis, and FLOW [husain2019; lincoff2023; perkovic2024]. STEP-HFpEF and STEP-HFpEF DM extend evidence to heart failure with preserved ejection fraction [kosiborod2023; kosiborod2024stephfpefdm] [knop2023oasis1]. MASH evidence has progressed from Newsome 2021 phase 2 to the phase 3 ESSENCE trial reported by Sanyal and colleagues in 2025; oral high-dose evidence for obesity comes from OASIS 1; knee osteoarthritis evidence comes from a dedicated phase 3 trial [newsome2021; sanyal2025essence; bliddal2024osteoarthritis].

Systematic reviews, network meta-analyses, and real-world studies provide convergent evidence. A 2025 systematic review and meta-analysis of cardiovascular and kidney outcomes across GLP-1 receptor agonists places semaglutide consistently in the upper tier of the class [colhoun2024selectkidney; lee2025cvkidneymeta] [pratley2018sustain7]. Direct head-to-head real-world data versus tirzepatide

consistently favor tirzepatide for weight loss in adults with overweight or obesity [rodriguez2024semavstirz] [wilding2021; wadden2021]. Real-world evidence in obesity and type 2 diabetes documents persistence, weight loss, and dose-titration patterns broadly similar to but typically less pronounced than the controlled-trial estimates [davies2021step2; rubino2021; garvey2022].

Evidence specifically supporting compounded preparations is limited. There is no parallel efficacy or safety randomized-trial program for compounded sterile semaglutide injections [aroda2019; capehorn2020sustain10; pratley2019pioneer4]. A real-world cohort of patients treated with compounded semaglutide documented weight loss in the same direction as the FDA-approved product, but at a lower magnitude and without controlled comparators or trial-grade safety adjudication [chun2025compoundedRWE] [smits2021] [weghuber2022]. Pharmacovigilance studies of compounded GLP-1 receptor agonists have documented disproportionate reporting of dosing errors and accidental overdose [mccall2026compoundedpv; mcintyre2026overdose]. Compounded use is therefore an extrapolation from the manufactured-product evidence base, justified case by case by documented patient-specific clinical factors that the manufactured product cannot accommodate [thomsen2025rwe]. Adverse-event reports associated with compounded products have been driven primarily by dosing errors in patient self-administration rather than by intrinsic pharmacology, but they reinforce the case for clinical supervision and against routine substitution [fda_compounding_risk_alert] [rubino2022step8; aroda2023safetypooled].

Major Compounded Semaglutide Clinical Studies

Study	Design	Participants	Duration	Finding
Lau et al. 2015 (J Med Chem), Discovery and preclinical characterization of semaglutide	Medicinal chemistry / preclinical PK and PD	—	Preclinical	Described Aib-2 substitution and C18 fatty-diacid acylation that yield albumin binding, DPP-4 resistance, and a circulating half-life of approximately one week in humans, the basis for once-weekly dosing [lau2015]
SUSTAIN-6 (Marso 2016, NEJM), Cardiovascular outcomes in T2D	Phase III, randomized, double-blind, placebo-controlled cardiovascular outcomes trial	3297	104 weeks	**For people with type 2 diabetes who already had high heart and stroke risk, semaglutide lowered the chance of cardiovascular death, heart attack, or stroke by about one quarter.** *Primary composite (CV death, nonfatal MI, nonfatal stroke) occurred in 6.6 percent of semaglutide-treated patients*

Study	Design	Participants	Duration	Finding
				vs 8.9 percent of placebo (HR 0.74; 95% CI 0.58, 0.95) [marso2016]
SUSTAIN 1 (Sorli 2017, Lancet Diabetes Endocrinol), Once-weekly subcutaneous monotherapy in T2D	Phase IIIa, randomized, double-blind, placebo-controlled	388	30 weeks	Mean HbA1c reduction approximately 1.5 percentage points (0.5 mg) and 1.6 percentage points (1.0 mg) vs placebo; significant body-weight reduction [sorli2017]
SUSTAIN 2 (Ahrén 2017, Lancet Diabetes Endocrinol), Semaglutide vs sitagliptin as add-on to metformin or thiazolidinediones	Phase IIIa, 56-week, double-blind	1231	56 weeks	Significantly greater HbA1c and body-weight reductions with semaglutide vs sitagliptin [ahren2017]
PIONEER 1 (Aroda 2019, Diabetes Care), Oral semaglutide monotherapy in T2D	Phase IIIa, 26-week, randomized, double-blind, placebo-controlled	703	26 weeks	Dose-dependent HbA1c reduction (−0.6 to −1.1 percent vs placebo) and body-weight reduction with oral semaglutide 3, 7, and 14 mg [aroda2019]
PIONEER 6 (Husain 2019, NEJM), Oral semaglutide cardiovascular outcomes in T2D	Phase III, randomized, double-blind, placebo-controlled cardiovascular outcomes trial	3183	Median 15.9 months	**In high-risk people with type 2 diabetes, oral semaglutide did not increase cardiovascular death, heart attack, or stroke compared with placebo, which helped support cardiovascular safety.** *Noninferiority for primary composite (CV death, nonfatal MI, nonfatal stroke); HR 0.79 (95% CI 0.57, 1.11) [husain2019]*
STEP 1 (Wilding 2021, NEJM), Once-weekly subcutaneous semaglutide 2.4 mg in adults with	Phase III, randomized, double-blind, placebo-controlled	1961	68 weeks	**Adults taking weekly semaglutide lost about 15 percent of their body weight over 68 weeks.** *Mean body-weight change −14.9 percent with semaglutide vs −2.4*

Study	Design	Participants	Duration	Finding
overweight or obesity without diabetes				*percent with placebo; 86.4 percent vs 31.5 percent achieved ≥5 percent loss [wilding2021]*
STEP 2 (Davies 2021, Lancet), Semaglutide 2.4 mg in adults with T2D plus overweight or obesity	Phase III, randomized, double-blind, double-dummy, placebo-controlled	1210	68 weeks	**Adults with type 2 diabetes and obesity lost about 10 percent of their body weight on semaglutide 2.4 mg.** *Mean body-weight change −9.6 percent with semaglutide 2.4 mg vs −3.4 percent with placebo; significantly greater HbA1c reduction [davies2021step2]*
STEP 3 (Wadden 2021, JAMA), Semaglutide 2.4 mg plus intensive behavioral therapy	Phase III, randomized, double-blind, placebo-controlled	611	68 weeks	Mean body-weight change −16.0 percent with semaglutide vs −5.7 percent with placebo plus the same intensive behavioral therapy [wadden2021]
STEP 4 (Rubino 2021, JAMA), Weight-loss maintenance	Phase III, randomized withdrawal after 20-week run-in	803	48 weeks post-randomization	**People who stopped semaglutide after initial weight loss regained much of the weight within the next year.** *Continued semaglutide produced an additional −7.9 percent weight change vs +6.9 percent regain with placebo switch (difference 14.8 percentage points) [rubino2021]*
STEP 5 (Garvey 2022, Nature Medicine), Two-year durability	Phase III, randomized, double-blind, placebo-controlled	304	104 weeks	**People who continued semaglutide kept about 15 percent weight loss through two years.** *Mean body-weight change −15.2 percent with semaglutide vs −2.6 percent with placebo; durability of effect demonstrated through two years [garvey2022]*
STEP TEENS (Weghuber 2022, NEJM), Adolescents	Phase III, randomized, double-blind,	201	68 weeks	Mean BMI change −16.1 percent with semaglutide vs +0.6 percent

Study	Design	Participants	Duration	Finding
12 to <18 years with obesity	placebo-controlled			with placebo; supports adolescent Wegovy indication [weghuber2022]
SELECT (Lincoff 2023, NEJM), Cardiovascular outcomes in obesity without diabetes	Phase III, randomized, double-blind, placebo-controlled cardiovascular outcomes trial	17604	Median 39.8 months	**Adults with obesity and prior cardiovascular disease, but without diabetes, had about 20 percent fewer cardiovascular death, heart attack, or stroke events on semaglutide.** *Primary composite (CV death, nonfatal MI, nonfatal stroke) in 6.5 percent of semaglutide vs 8.0 percent of placebo; HR 0.80 (95% CI 0.72, 0.90; P<0.001) [lincoff2023]*
FLOW (Perkovic 2024, NEJM), Kidney outcomes in T2D plus CKD	Phase III, randomized, double-blind, placebo-controlled outcomes trial	3533	Median 3.4 years	**In people with type 2 diabetes and kidney disease, semaglutide lowered the risk of major kidney outcomes by about 24 percent.** *Composite kidney outcome occurred 24 percent less often with semaglutide (HR 0.76; 95% CI 0.66, 0.88); cardiovascular death also reduced [perkovic2024]*
STEP-HFpEF (Kosiborod 2023, NEJM), Heart failure with preserved ejection fraction plus obesity	Phase III, randomized, double-blind, placebo-controlled	529	52 weeks	Greater improvement in KCCQ clinical summary score and six-minute walk distance, greater weight loss, and reduced inflammation versus placebo [kosiborod2023]
Newsome 2021 (NEJM), Phase 2 trial of subcutaneous semaglutide in NASH	Phase 2, randomized, double-blind, placebo-controlled	320	72 weeks	NASH resolution without worsening fibrosis in 59 percent of the 0.4 mg arm vs 17 percent on placebo; fibrosis improvement endpoint not statistically significant [newsome2021]
SUSTAIN 3 (Ahmann 2018, Diabetes Care),	Phase IIIa, 56-week, open-label, randomized	813	56 weeks	Greater HbA1c reduction (−1.5% vs −0.9%) and greater body-weight reduction with once-weekly

Study	Design	Participants	Duration	Finding
Semaglutide vs exenatide ER in T2D	active-comparator			semaglutide 1.0 mg vs exenatide ER 2.0 mg [ahmann2018sustain3]
SUSTAIN 4 (Aroda 2017, Lancet Diabetes Endocrinol), Semaglutide vs insulin glargine in insulin-naive T2D	Phase IIIa, 30-week, open-label, randomized active-comparator	1089	30 weeks	Greater HbA1c reduction with semaglutide (0.5 mg or 1.0 mg) versus titrated insulin glargine, with weight loss on semaglutide vs weight gain on insulin [aroda2017sustain4]
SUSTAIN 7 (Pratley 2018, Lancet Diabetes Endocrinol), Semaglutide vs dulaglutide in T2D	Phase IIIb, 40-week, open-label, randomized active-comparator	1201	40 weeks	Greater HbA1c reduction and greater body-weight reduction with semaglutide (0.5 mg vs dulaglutide 0.75 mg; 1.0 mg vs dulaglutide 1.5 mg) [pratley2018sustain7]
SUSTAIN 10 (Capehorn 2020, Diabetes Metab), Semaglutide vs liraglutide in T2D	Phase IIIb, 30-week, open-label, randomized active-comparator	577	30 weeks	Greater HbA1c reduction (−1.7% vs −1.0%) and greater weight reduction with once-weekly semaglutide 1.0 mg vs once-daily liraglutide 1.2 mg in patients on 1, 3 oral agents [capehorn2020sustain10]
PIONEER 4 (Pratley 2019, Lancet), Oral semaglutide vs subcutaneous liraglutide and placebo in T2D	Phase IIIa, 52-week, randomized, double-blind active-comparator	711	52 weeks	Oral semaglutide 14 mg noninferior to subcutaneous liraglutide 1.8 mg for HbA1c at 26 weeks and superior for body-weight reduction; superior to placebo on both endpoints [pratley2019pioneer4]
PIONEER 5 (Mosenzon 2019, Lancet Diabetes Endocrinol), Oral semaglutide in moderate renal impairment	Phase IIIa, 26-week, randomized, double-blind, placebo-controlled	324	26 weeks	HbA1c reduction approximately 1.0 percentage point and body-weight reduction approximately 3.4 kg with oral semaglutide 14 mg in T2D plus moderate renal impairment; safety profile consistent with the broader program [mosenzon2019pioneer5]
PIONEER PLUS (Aroda 2023,	Phase IIIb, 52-week,	1606	52 weeks	Greater HbA1c reduction with oral semaglutide 25 mg and 50 mg vs

Study	Design	Participants	Duration	Finding
Lancet), Higher-dose oral semaglutide (25 mg, 50 mg vs 14 mg) in T2D	randomized, double-blind			the 14 mg dose; tolerability profile consistent with the lower dose [aroda2023pioneerplus]
STEP 8 (Rubino 2022, JAMA), Semaglutide 2.4 mg vs liraglutide 3.0 mg in overweight or obesity without diabetes	Phase IIIb, 68-week, open-label, randomized active-comparator	338	68 weeks	Greater weight loss with weekly semaglutide 2.4 mg than daily liraglutide 3.0 mg (mean −15.8% vs −6.4%); higher proportion achieving ≥10 and ≥15 percent loss [rubino2022step8]
STEP-HFpEF DM (Kosiborod 2024, NEJM), Semaglutide in obesity-related HFpEF with type 2 diabetes	Phase III, 52-week, randomized, double-blind, placebo-controlled	616	52 weeks	Greater improvement in KCCQ clinical summary score, weight, and six-minute walk distance with semaglutide vs placebo in patients with HFpEF, obesity, and T2D [kosiborod2024stephfpefdm]
ESSENCE (Sanyal 2025, NEJM), Phase 3 semaglutide 2.4 mg in MASH with fibrosis	Phase 3, randomized, double-blind, placebo-controlled, biopsy-endpoint	—	72 weeks	Significantly higher rates of MASH resolution without worsening of fibrosis and of fibrosis improvement without worsening of MASH with semaglutide vs placebo at 72 weeks [sanyal2025essence]
OASIS 1 (Knop 2023, Lancet), Oral semaglutide 50 mg in overweight or obesity without diabetes	Phase 3, 68-week, randomized, double-blind, placebo-controlled	667	68 weeks	Mean body-weight change −15.1 percent with oral semaglutide 50 mg vs −2.4 percent with placebo, comparable to subcutaneous Wegovy 2.4 mg [knop2023oasis1]
Bliddal 2024 (NEJM), Semaglutide 2.4 mg in obesity-associated knee osteoarthritis	Phase 3, 68-week, randomized, double-blind, placebo-controlled	407	68 weeks	Greater weight loss and greater reduction in WOMAC pain scores with semaglutide vs placebo in adults with obesity and knee osteoarthritis [bliddal2024osteoarthritis]
Rodriguez 2024 (JAMA Intern Med), Semaglutide vs	Retrospective cohort of EMR-	~18,000	12 months	Greater weight reduction with tirzepatide than semaglutide at 3, 6, and 12 months in adults with

Study	Design	Participants	Duration	Finding
tirzepatide for weight loss (real-world)	linked claims data			overweight or obesity [rodriguez2024semavstirz]
Vilsbøll 2018 (Diabetes Obes Metab), Retinopathy risk and rapid HbA1c reduction	Post-hoc analysis of SUSTAIN-6	3297	104 weeks	Retinopathy-complication signal concentrated in patients with pre-existing retinopathy and rapid HbA1c reduction, consistent with the 'early worsening' phenomenon [vilsboll2018retinopathy]
Lee 2025 (Diabetes Care), Systematic review and meta-analysis of GLP-1 RA CV and kidney outcomes	Systematic review and meta-analysis of randomized cardiovascular and kidney outcomes trials	—	Cross-trial	GLP-1 receptor agonists as a class reduce major adverse cardiovascular events, kidney composite outcomes, and all-cause mortality; semaglutide effects are consistent with the class average and numerically toward the upper end for several endpoints [lee2025cvkidneymeta]

Compounded Semaglutide Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Semaglutide has a circulating half-life of approximately one week (around 165 hours), driven by reversible albumin binding (>99 percent) and DPP-4 resistance [lau2015; hall2018pk]. After once-weekly subcutaneous administration, steady state is reached after approximately 4, 5 weeks. Absolute bioavailability after subcutaneous administration is approximately 89 percent [hall2018pk; fda_label_ozempic] [fda_label_rybelsus].

Oral semaglutide (Rybelsus) co-formulated with the absorption enhancer salcaprozate sodium (SNAC) achieves bioavailability in the approximate range of 0.4, 1 percent, with high intra- and inter-individual variability [fda_label_rybelsus]. The tablet must be taken on an empty stomach with up to 4 oz of plain water at least 30 minutes before any other food, beverage, or oral medication; co-ingestion materially reduces absorption [buckley2018stomachabsorption]. Steady-state oral exposure approximates that of low subcutaneous doses. Mechanistic stomach-absorption work shows SNAC produces a transient local pH and permeability change adjacent to the tablet, with the intact peptide absorbed across the gastric epithelium.

Elimination is via proteolytic degradation of the peptide backbone and beta-oxidation of the fatty-acid side chain, with metabolites cleared through both urine and feces. Renal impairment does not require dose adjustment; oral semaglutide pharmacokinetics in moderate renal impairment were characterized within

the PIONEER 5 trial [overgaard2021oralpk; mosenzon2019pioneer5]. Population-PK analyses found no clinically meaningful effect of age, sex, race, or body weight on exposure that would warrant fixed-dose adjustment.

Compounded sterile injections are not bioequivalent to manufactured Ozempic or Wegovy [fda_label_wegovy]. PK from a compounded vial reflects the specific formulation, salt form, and concentration prepared and cannot be assumed to match published manufactured-product values [fda_compounding_risk_alert].

Pharmacodynamics

Pharmacodynamic effects scale with dose and exposure. Postprandial and fasting glucose lowering occur via glucose-dependent insulin secretion and glucagon suppression, with HbA1c reductions of approximately 1, 1.8 percentage points across the SUSTAIN and PIONEER programs depending on dose, indication, and comparator. The higher-dose oral formulations (25 mg, 50 mg) extend efficacy beyond the 14 mg dose [aroda2023pioneerplus] [aroda2019].

Body-weight reduction, central to the chronic-weight-management indication, scales from approximately 5, 7 percent at 1.0 mg in T2D populations to approximately 15 percent at 2.4 mg in the STEP weight-management population at 68 weeks [wilding2021; davies2021step2; garvey2022]. Effects on appetite and food preference (reduced palatable-food intake, reduced craving) parallel the weight loss. In a randomized direct comparison against once-daily liraglutide 3.0 mg, weekly semaglutide 2.4 mg produced substantially greater weight reduction (mean −15.8% versus −6.4%) at 68 weeks [friedrichsen2021appetite; rubino2022step8] [sorli2017]. Cessation of therapy after one year of treatment leads to substantial weight regain over the following year, framing semaglutide as a chronic rather than time-limited therapy [wilding2022step1ext] [ahren2017; pratley2019pioneer4].

Cardiovascular pharmacodynamics include modest reductions in systolic blood pressure (approximately 3, 6 mmHg), reductions in inflammatory markers (notably C-reactive protein, prominent in STEP-HFpEF), and the major adverse cardiovascular event reductions observed in SUSTAIN-6 and SELECT [marso2016]. A pre-specified SELECT kidney sub-analysis demonstrated reduction in a composite kidney outcome in the obesity-plus-CVD population without diabetes [lincoff2023]. In the FLOW trial in T2D plus CKD, semaglutide reduced the composite kidney outcome by 24 percent [kosiborod2023; colhoun2024selectkidney; perkovic2024].

↓↑ Comparing Compounded Semaglutide Formulations

Manufactured Ozempic and Wegovy are supplied as pre-filled multi-dose pens with built-in dose-step mechanisms that limit per-dose error. Rybelsus is a tablet co-formulated with SNAC that is taken on an empty stomach with strict water and timing requirements to achieve adequate absorption [fda_label_rybelsus].

Compounded subcutaneous semaglutide preparations differ from manufactured products in concentration, salt form (semaglutide acetate, semaglutide sodium, or other forms), excipients, container-closure system, and dose-delivery mechanism [fda_label_ozempic; fda_label_wegovy; fda_compounding_risk_alert]. Patients self-administering from a multi-dose vial measure each dose with a separate syringe, which introduces dosing-error risk that the manufactured pen mechanically prevents. The FDA has received hundreds of adverse-event reports related to compounded GLP-1 receptor agonists, with dosing errors a recurring theme.

Patients transitioning between manufactured and compounded preparations (or vice versa) should be reassessed for tolerability and effect [fda_compounding_risk_alert]. Bioequivalence cannot be assumed.

Compounded Semaglutide Storage and Handling

Manufactured Ozempic and Wegovy pens are refrigerated at 2, 8 °C prior to first use; once in use they may be stored at room temperature (15, 30 °C) or refrigerated for a labeled in-use period (typically 56 days). Pens should not be frozen. Rybelsus tablets are stored at controlled room temperature in the original blister packaging to protect from moisture [fda_label_rybelsus].

Compounded sterile injections of semaglutide are stored per the compounding pharmacy's stability data and label, typically refrigerated, with beyond-use dating established under USP <797> [fda_label_ozempic; fda_label_wegovy; usp_797]. Stability of a compounded preparation depends on the specific formulation; patient instructions must reflect the BUD on the dispensed product.

Compounded Semaglutide Compounding & Operations

503A compounding

Compounded semaglutide injections are prepared under 503A on patient-specific prescriptions in state-licensed compounding pharmacies. RonanRx prepares sterile injectable preparations per USP General Chapter <797>, the official compendial standard for sterile pharmaceutical compounding, with documented active ingredient sourcing, sterility and endotoxin testing per the pharmacy's quality management system, and finished-product release criteria [usp_797].

Beyond-use dating, ingredient identity verification, and stability assessment follow USP <797> requirements. Each compounded batch is documented per state board of pharmacy retention rules with full traceability from active pharmaceutical ingredient lot through dispensing [usp_797].

Per FDA guidance, compounded versions of an FDA-approved drug are generally restricted to situations where a prescriber has documented that the manufactured product cannot meet the identified patient's medical need [fda_essentially_a_copy]. The FDA's February 2025 declaratory order resolving the semaglutide injection shortage, and the subsequent guidance setting compliance deadlines for

compounders, narrowed the operating space further. Routine substitution of a compounded preparation for an FDA-approved product is not a permissible basis. FDA pharmacovigilance and pharmacy-led analyses of FAERS reports specific to compounded GLP-1 receptor agonists have flagged dosing errors and accidental overdose as the dominant patterns [fda_compounding_risk_alert; mccall2026compoundedpv; mcintyre2026overdose] [fda503a; fda_shortage_resolution_2025].

Pharmacist review

Each prescription for compounded semaglutide undergoes pharmacist review prior to dispensing. The review confirms a documented patient-specific clinical reason that the manufactured product cannot meet (excipient sensitivity, a strength not commercially available, or another individualized factor), absence of contraindications (personal or family history of medullary thyroid carcinoma, MEN 2, pregnancy, prior serious hypersensitivity to semaglutide), and that the prescribed regimen falls within the FDA-labeled maximum doses for the relevant indication.

RonanRx does not fill prescriptions that read as routine substitution of compounded semaglutide for an FDA-approved product without a documented clinical rationale, consistent with FDA guidance on compounded copies of commercially available drugs and the FDA's post-shortage compounding posture [fda_essentially_a_copy; fda_shortage_resolution_2025].

Quality and traceability

Active pharmaceutical ingredients are sourced from FDA-registered facilities with documented certificates of analysis covering identity, potency, related substances, and bioburden. Each compounded sterile batch is recorded with lot numbers traceable to API source, compounding date, sterility and endotoxin test results, beyond-use date, and dispensing pharmacist of record. Finished product lot records are retained per state board of pharmacy retention requirements.

Cold chain

Compounded semaglutide sterile injections are cold-chain products. They are stored and shipped refrigerated (2, 8 °C) with documented temperature monitoring through dispensing. Patients are instructed to refrigerate the product on receipt, observe the labeled beyond-use date, and follow the dispensing pharmacy's instructions for in-use handling. Manufactured Ozempic and Wegovy pens follow the same cold-chain pattern with manufacturer-specific in-use room-temperature allowances [fda_label_ozempic; fda_label_wegovy].

Frequently Asked Questions About Compounded Semaglutide

Is compounded semaglutide the same as Ozempic, Wegovy, or Rybelsus?

No. Ozempic, Wegovy, and Rybelsus are FDA-approved manufactured products. Compounded semaglutide preparations are pharmacy-prepared on a patient-specific prescription, are not FDA-approved, and are not bioequivalent to the manufactured products [fda_label_ozempic; fda_label_wegovy; fda_label_rybelsus]. They differ in formulation, salt form, concentration, container, and dose-delivery mechanism [fda503a].

When is a compounded version of semaglutide appropriate?

Per FDA guidance, a compounded version of an FDA-approved drug is generally restricted to situations where the prescriber documents a patient-specific clinical need that the manufactured product cannot meet, for example, a documented sensitivity to a manufactured-product excipient or a strength not commercially available [fda_essentially_a_copy; fda_shortage_resolution_2025]. Patient preference for a compounded product is not a permissible basis on its own.

How well does semaglutide work for weight loss?

In the pivotal STEP 1 trial of subcutaneous semaglutide 2.4 mg (Wegovy) in adults with overweight or obesity without diabetes, mean body-weight change at 68 weeks was −14.9 percent with semaglutide versus −2.4 percent with placebo [wilding2021; garvey2022]. Approximately 86 percent of semaglutide-treated participants achieved at least 5 percent weight loss versus 32 percent on placebo. Two-year durability was demonstrated in STEP 5.

What are the most common side effects?

Gastrointestinal effects, nausea, vomiting, diarrhea, constipation, are the most common adverse events and dominate the tolerability profile. They are usually mild to moderate, concentrated in the first weeks of each dose step, and the leading cause of discontinuation across trials [wilding2021; smits2021].

Who should not take semaglutide?

Semaglutide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), in patients with a prior serious hypersensitivity reaction to semaglutide or any of its excipients, and in pregnancy [fda_label_ozempic; fda_label_wegovy]. Caution and clinical judgment are required in patients with a history of pancreatitis, severe gastrointestinal dysmotility, active high-risk diabetic retinopathy, or active gallbladder disease.

Does semaglutide reduce cardiovascular risk?

Yes, in the populations studied. SUSTAIN-6 demonstrated a 26 percent relative reduction in major adverse cardiovascular events in adults with type 2 diabetes at high cardiovascular risk [marso2016]. SELECT (2023) demonstrated a 20 percent relative reduction in major adverse cardiovascular events in adults with obesity and established cardiovascular disease but without diabetes, supporting an FDA-approved cardiovascular risk-reduction indication on Wegovy [lincoff2023].

Does RonanRx sell compounded semaglutide directly to patients?

No. Compounded semaglutide requires a patient-specific prescription written by a licensed doctor for an identified patient with a documented clinical reason that the FDA-approved manufactured product is not appropriate, plus pharmacist review before dispensing [fda_essentially_a_copy]. RonanRx is not a direct-to-consumer storefront [fda503a].

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How to Access Compounded Semaglutide

Compounded Compounded Semaglutide is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed Compounded Semaglutide, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)