



CLINICAL MONOGRAPH · GROWTH-HORMONE AXIS (UNDER FDA REVIEW)

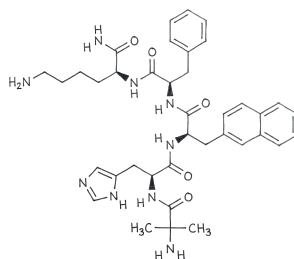
Ipamorelin

Selective ghrelin-receptor agonist with pharmacy review

Ipamorelin is a small synthetic peptide, five amino acids long, that was designed in the late 1990s to tell the pituitary gland to release growth hormone [gobburu1999]. Unlike older growth-hormone-releasing peptides, ipamorelin was engineered to be selective: in early studies it released growth hormone without meaningfully raising prolactin, cortisol, or ACTH [raun1998].

It was developed by Novo Nordisk and tested in humans for catabolic conditions, but its only published phase 2 trial, in postoperative ileus after bowel surgery, did not meet its primary endpoint, and clinical development was discontinued [beck2014]. Ipamorelin has never received FDA marketing authorization.

Ipamorelin has no FDA approval in the United States. This ingredient is part of an evolving FDA review process. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance.



EVIDENCE POSTURE

EMERGING

PRECLINICAL

REVIEWED 2026-05-11



State-licensed
503A



Pharmacist
reviewed



Doctor
led



Cold-chain
ready



Patient choice
preserved



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FOR CLINICIANS

Ipamorelin is a synthetic pentapeptide (Aib-His-D-2-Nal-D-Phe-Lys-NH₂) developed by Novo Nordisk in the mid-1990s as NNC 26-0161 and first characterized by Raun et al. (European Journal of Endocrinology, 1998) [raun1998]. It binds the growth hormone secretagogue receptor type 1a (GHS-R1a), the cognate receptor for ghrelin, and releases growth hormone from somatotrophs in a manner similar to GHRP-6 and GHRP-2, but with markedly greater receptor selectivity: in the original Raun characterization, ipamorelin released GH in swine and rats with no significant elevation in prolactin, ACTH, cortisol, or FSH/LH at GH-releasing doses. The first human pharmacokinetic/pharmacodynamic data were published by Gobburu et al. (Pharmaceutical Research, 1999) [gobburu1999] in healthy adult volunteers and supported a short plasma half-life (~2 hours) with dose-dependent GH and IGF-1 responses.

Clinical development moved into catabolic-state indications. The largest published trial was a phase 2 randomized controlled proof-of-concept study by Beck et al. (International Journal of Colorectal Disease, 2014) [beck2014] of intravenous ipamorelin for the management of postoperative ileus after bowel resection. The trial did not meet its primary efficacy endpoint and clinical development was subsequently discontinued. Preclinical mechanistic and translational work supporting the POI hypothesis [venkova2009, greenwood2012] and visceral nociception [mohammadi2020] continued, and a glucocorticoid-induced bone-loss rat model [andersen2001] suggested anabolic potential that was never tested in humans. Ipamorelin has never received FDA approval for any indication.

Ipamorelin has no FDA approval in the United States. This ingredient is part of an evolving FDA review process. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance.

☞ Why Personalized Ipamorelin

The evidence base for ipamorelin includes small human pharmacology studies and preclinical work, but no FDA-approved indication. Its selectivity claims do not remove the need for patient-specific rationale, route review, and pharmacist judgment.

Physicians may submit patient-specific prescription requests for ipamorelin for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, supported by patient-specific documentation, and approved by the dispensing pharmacy. Availability is determined case by case. This is not a consumer access promise; it is a clinical, sourcing, formulation, and regulatory review process. This ingredient is part of an evolving FDA review process for peptide-related bulk substances used in compounding.

The regulated path for ipamorelin is not a consumer stack or clinic menu. A physician may submit a prescription request, and the pharmacy decides case by case whether it can be prepared and dispensed.



⚡ Quick Facts About Ipamorelin

Category: Selective ghrelin (GHS-R1a) receptor agonist, growth hormone secretagogue

Active ingredient: Ipamorelin, a synthetic 5-amino-acid pentapeptide (Aib-His-D-2-Nal-D-Phe-Lys-NH₂) developed by Novo Nordisk as NNC 26-0161

FDA-approved branded forms: None. Ipamorelin has never received FDA approval for any indication and clinical development was discontinued.

Route: Subcutaneous or intravenous in published studies; no labeled route exists

Evidence posture: Emerging and preclinical. Initial selectivity characterization in rats and pigs [raun1998]; phase 1 human PK/PD in healthy volunteers [gobburu1999]; phase 2 clinical trial in postoperative ileus failed its primary endpoint [beck2014]. No phase 3 program.

FDA-approval status: Category 2, evolving FDA review process. Valid patient-specific prescription required; supporting clinical rationale may be requested.

Compounded under: Not currently compoundable under 503A. RonanRx does not dispense ipamorelin pending FDA reclassification to Category 1.

WADA status: Category 2, evolving FDA review process. Valid patient-specific prescription required; supporting clinical rationale may be requested.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Physicians may submit patient-specific prescription requests for Ipamorelin for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case.

- **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 Ipamorelin?

Ipamorelin is a synthetic 5-amino-acid pentapeptide with the sequence Aib-His-D-2-Nal-D-Phe-Lys-NH₂ (aminoisobutyric acid, histidine, D-2-naphthyl-alanine, D-phenylalanine, lysine, with a C-terminal amide). It was developed at Novo Nordisk as compound NNC 26-0161 and disclosed in the peer-reviewed literature by Raun and colleagues in 1998 [raun1998]. Structurally it is unrelated to ghrelin itself (a 28-amino-acid acylated peptide) but binds the same receptor, the growth hormone secretagogue receptor type 1a (GHS-R1a), and reproduces ghrelin's growth-hormone-releasing action.

Ipamorelin has never received marketing authorization from FDA, EMA, or any other major regulator for any indication. It is not available as a manufactured pharmaceutical product. In published studies it has been administered intravenously and subcutaneously; there is no FDA-approved formulation, route, or dose.

⚙️ How Ipamorelin Works

Ipamorelin is a selective agonist at the growth hormone secretagogue receptor type 1a (GHS-R1a), the same G-protein-coupled receptor activated by endogenous ghrelin [raun1998]. GHS-R1a is expressed on somatotroph cells of the anterior pituitary, where its activation triggers calcium influx and inositol phosphate signaling that release pre-formed growth hormone into the circulation. GHS-R1a is also expressed in the hypothalamus, where it modulates GHRH release, and in peripheral tissues including the gastrointestinal tract.

What distinguished ipamorelin from earlier growth-hormone-releasing peptides (GHRP-6, GHRP-2, hexarelin) in the Raun et al [raun1998]. (1998) characterization was its receptor selectivity profile: at doses that produced a maximal GH response in swine and rats, ipamorelin did not significantly elevate prolactin, ACTH, cortisol, FSH, or LH, whereas GHRP-6 and GHRP-2 produced measurable cross-axis activation. This selectivity is the central pharmacological claim for the molecule. Subsequent characterization confirmed the selectivity profile in rodent models [andersen2001] and in chronic-treatment studies [jimenez2002].

🕒 Biological Role of Ipamorelin

The growth hormone secretagogue receptor was cloned in the late 1990s as the orphan receptor activated by a class of synthetic GH-releasing peptides. Its endogenous ligand, ghrelin, was identified shortly afterward



as an acylated 28-amino-acid peptide from oxyntic cells of the stomach that signals nutrient state, drives appetite, and amplifies the pulsatile release of pituitary growth hormone. The receptor is expressed in the anterior pituitary, hypothalamic arcuate nucleus, area postrema, vagal afferents, and enteric nervous system.

The therapeutic rationale for synthetic GHS-R1a agonists is to replicate or amplify ghrelin's downstream effects without administering the larger, less-stable native peptide. Hexarelin, GHRP-6, and GHRP-2 were earlier peptidic agonists with broad pituitary effects (GH plus prolactin, ACTH, cortisol); ipamorelin's selectivity profile was the key design feature that distinguished it from those earlier compounds [raun1998]. The contemporary FDA-approved orally bioavailable ghrelin agonist anamorelin is approved in some jurisdictions (Japan) for cancer cachexia and shares the mechanism class without the selectivity profile of ipamorelin.

A Detailed Mechanism of Ipamorelin

GHS-R1a is a class A G-protein-coupled receptor that couples primarily to Gαq/11. Agonist binding activates phospholipase C, generates inositol 1,4,5-trisphosphate and diacylglycerol, releases intracellular calcium, and triggers vesicular release of pre-formed growth hormone from anterior pituitary somatotrophs [raun1998]. Endogenous ligand is octanoyl-modified ghrelin secreted predominantly from oxyntic cells of the stomach. Ahnfelt-Rønne et al. (2001) [ahnfelt2001] examined whether GH-releasing peptides act upstream as ghrelin secretagogues; the data supported direct GHS-R1a agonism rather than ghrelin-mediated indirect action as the primary mechanism for ipamorelin.

Mechanism beyond GH release. Ipamorelin's GH-releasing action engages the downstream GH/IGF-1 axis: in healthy adults, single doses produced dose-dependent GH peaks and downstream IGF-1 elevation over the dosing interval [gobburu1999]. Preclinical data demonstrated insulin-releasing action on isolated pancreatic islets [adehgate2004] and effects on the hypothalamic-pituitary-testicular axis in fish models [gouda2024_fish] suggesting some cross-axis activity at higher doses. Andersen et al. (2001) [andersen2001] showed that ipamorelin counteracted glucocorticoid-induced reductions in bone formation in adult rats, an effect attributed to restored GH/IGF-1 signaling at the osteoblast. Johansen et al. (2003) [johansen2003] reported GH hypersecretion and downstream GH receptor resistance in streptozotocin-diabetic mice given ipamorelin, illustrating context-dependent responsiveness of the GH/IGF-1 axis to chronic GHS-R1a agonism [raun1998].

Gastrointestinal mechanism in postoperative ileus. GHS-R1a is expressed on enteric neurons, and ghrelin agonism accelerates gastric emptying and small-bowel transit in animal models. Venkova et al. (2009) [venkova2009] and Greenwood-Van Meerveld et al. (2012) [greenwood2012] established the prokinetic effect of ipamorelin in a rodent postoperative ileus model, the mechanistic rationale that motivated the Beck et al. (2014) phase 2 trial in bowel-resection patients [beck2014]. Mohammadi et al. (2020)



[mohammadi2020] extended the GI rationale by demonstrating attenuation of visceral and somatic nociception by ghrelin mimetics including ipamorelin [raun1998].

Pharmacokinetics. The only published human PK data are from Gobburu et al. (1999) [gobburu1999], who studied intravenous ipamorelin in healthy adult volunteers [raun1998]. Plasma half-life was approximately 2 hours, distribution was approximately one body-water volume, and GH and IGF-1 responses were dose-dependent. The short half-life is consistent with the molecule's small size and lack of fatty-acid modification. There is no published population PK analysis, no oral bioavailability data, and no subcutaneous PK in any human disease population. Healthy-adult IGF-1 PK in chronic dosing has not been published in peer review.

🕒 Ipamorelin Research History

Ipamorelin was developed at Novo Nordisk in the mid-1990s as NNC 26-0161 and disclosed in peer review by Raun and colleagues (European Journal of Endocrinology, 1998) [raun1998]. The discovery paper characterized the molecule's receptor binding, GH-releasing potency, and, importantly, its lack of cross-activation of prolactin, ACTH, cortisol, FSH, and LH at GH-releasing doses in swine and rats. The first human phase 1 PK/PD study followed in 1999 (Gobburu et al., Pharmaceutical Research) [gobburu1999], establishing single-dose PK and dose-dependent GH responses in healthy adult volunteers [mavrych2026].

Preclinical translational work expanded through the early 2000s. Andersen et al. (2001) [andersen2001] reported that chronic ipamorelin partially restored bone formation in glucocorticoid-treated adult rats, a finding that informed the hypothesis that ipamorelin might be useful for steroid-induced catabolic states. Jiménez-Reina et al. (2002) [jimenez2002] characterized somatotroph responsiveness during chronic ipamorelin treatment in young female rats. Johansen et al. (2003) [johansen2003] studied the GH/IGF-1 axis response in streptozotocin-diabetic mice. Adeghate and Ponery (2004) [adeghate2004] reported a direct pancreatic insulin-releasing action of ipamorelin on isolated rat islets. Ahnfelt-Rønne et al. (2001) [ahnfelt2001] addressed whether GHRPs (including ipamorelin) act as ghrelin secretagogues, supporting direct GHS-R1a engagement as the primary mechanism [sinha2020].

Translation into a clinical indication centered on postoperative ileus. Venkova et al. (2009) [venkova2009] and Greenwood-Van Meerveld et al. (2012) [greenwood2012] reported preclinical efficacy of ipamorelin in rodent POI models. The phase 2 proof-of-concept trial, Beck et al. (2014) [beck2014], randomized 114 adults undergoing bowel resection to intravenous ipamorelin or placebo and evaluated time to first bowel movement and gastrointestinal recovery composites. The trial did not meet its primary efficacy endpoint; clinical development of ipamorelin was subsequently discontinued. Mohammadi et al. (2020) [mohammadi2020] continued mechanistic work on visceral nociception with ghrelin mimetics including ipamorelin; Lu et al. (2024) [lu2024] reported anti-cachexia effects of ipamorelin in a ferret cisplatin model, contributing to the broader anamorelin-class literature without restarting ipamorelin clinical development [rahman2026].



Doping-control and supply-chain literature. Ipamorelin appears repeatedly in the World Anti-Doping Agency-funded analytical and pharmacovigilance literature (Thomas, Krug, Semenistaya, Gajda, and colleagues) [krug2018, gajda2019], including analyses of seized black-market peptide products that document identity, dose, and purity discrepancies in the unregulated supply chain. Practitioner-facing reviews on the broader unregulated peptide market catalog the safety and regulatory concerns specific to growth hormone secretagogues sold outside the prescription drug pathway [mendias2026; mayfield2026; coutinho2026].

📅 Ipamorelin Timeline

- 1998** • Raun et al [raun1998]. publish the discovery and characterization of ipamorelin (NNC 26-0161) in *European Journal of Endocrinology*, the first selective growth hormone secretagogue, releasing GH in swine and rats without significant elevation in prolactin, ACTH, cortisol, FSH, or LH
- 1999** • Gobburu et al [gobburu1999]. (Pharmaceutical Research) publish the first phase 1 PK/PD study of ipamorelin in healthy adult human volunteers, dose-dependent GH/IGF-1 responses, plasma half-life approximately 2 hours
- 2001** • Andersen et al [andersen2001]. (Growth Hormone & IGF Research) report that ipamorelin counteracts glucocorticoid-induced decrease in bone formation in adult rats, informing the hypothesis of utility in steroid-induced catabolic states
- 2001** • Ahnfelt-Rønne et al [ahnfelt2001]. (Endocrine) address whether GH-releasing peptides act as ghrelin secretagogues, supporting direct GHS-R1a engagement as the primary mechanism for ipamorelin
- 2002** • Jiménez-Reina et al [jimenez2002]. (Histology and Histopathology) characterize somatotroph responses to chronic ipamorelin treatment in young female rats
- 2003** • Johansen et al [johansen2003]. (Experimental Diabetes Research) report GH hypersecretion and downstream GH receptor resistance in streptozotocin-diabetic mice given ipamorelin
- 2004** • Adeghate and Ponery (Neuro Endocrinology Letters) describe a direct insulin-releasing action of ipamorelin on isolated pancreatic islets from normal and diabetic rats [adeghate2004]
- 2009** • Venkova et al [venkova2009]. (J Pharmacol Exp Ther) report efficacy of ipamorelin in a rodent postoperative ileus model, the preclinical foundation for the subsequent phase 2 trial
- 2012** • Greenwood-Van Meerveld et al [greenwood2012]. (J Exp Pharmacol) extend the postoperative ileus rationale, demonstrating efficacy of ipamorelin on gastric dysmotility in a rodent POI model



- 2014 • Beck et al [beck2014]. (Int J Colorectal Dis) publish the phase 2 randomized proof-of-concept trial of intravenous ipamorelin in bowel-resection patients, primary efficacy endpoint not met; clinical development subsequently discontinued

- 2018 • Krug et al [krug2018]. (Growth Hormone & IGF Research) publish analytical characterization of seized black-market growth-hormone-releasing peptide products, documenting identity, purity, and labeling discrepancies in the unregulated supply chain

- 2019 • Gajda et al [gajda2019]. (Drug Testing and Analysis) report glycine-modified GH secretagogues identified in seized doping material, expanding the documented unregulated-supply-chain risk profile

- 2020 • Mohammadi et al [mohammadi2020]. (J Exp Pharmacol) demonstrate attenuation of visceral and somatic nociception by ghrelin mimetics including ipamorelin

- 2024 • Lu et al [lu2024]. (Physiology & Behavior) report inhibition of cisplatin-induced weight loss in ferrets by anamorelin and ipamorelin, recent preclinical anti-cachexia literature in the class

- 2025 • World Anti-Doping Agency Prohibited List confirms ipamorelin remains prohibited at all times under section S2 (peptide hormones, growth factors, related substances and mimetics, growth hormone secretagogues) [wada_prohibited_list_2025]

- 2026 • Practitioner-facing reviews on therapeutic peptides in orthopaedics, sports medicine, and gerontology consistently document ipamorelin's lack of FDA approval and its prominent use in unregulated wellness-clinic markets [mendias2026; mayfield2026; rahman2026; coutinho2026; mavrych2026]

📁 Clinical Contexts for Ipamorelin

Postoperative ileus following bowel resection EMERGING

Studied in a single phase 2 randomized proof-of-concept trial which did not meet its primary efficacy endpoint; clinical development discontinued.

Beck et al. (2014) [beck2014] randomized 114 adults undergoing open or laparoscopic bowel resection to intravenous ipamorelin or placebo and assessed time to first bowel movement and a composite GI recovery endpoint. The trial did not demonstrate a statistically significant benefit on its primary endpoint. The preclinical rationale [venkova2009] demonstrated prokinetic activity in rodent POI models, but the human trial failure ended development of ipamorelin for this indication. Ipamorelin has no marketing authorization for postoperative ileus in any jurisdiction [greenwood2012].



Growth hormone secretagogue testing / pituitary GH reserve assessment (research use)

EMERGING

Studied as a phase 1 PK/PD probe in healthy adult volunteers; not developed as a diagnostic product.

Gobburu et al. (1999) [gobburu1999] characterized single-dose intravenous ipamorelin PK and the GH/IGF-1 response in healthy adult volunteers, establishing the molecule's selectivity profile in humans (consistent with the preclinical Raun 1998 [raun1998] characterization). No diagnostic or therapeutic product was ever developed from this work.

Glucocorticoid-induced catabolism / bone loss **PRECLINICAL**

Preclinical evidence only.

Andersen et al. (2001) [andersen2001] reported that chronic ipamorelin partially counteracted glucocorticoid-induced reductions in bone formation in adult rats. The signal was never tested in a human trial. Ipamorelin is not appropriate for this indication outside research.

Cancer cachexia / chemotherapy-induced weight loss **PRECLINICAL**

Preclinical evidence in a ferret cisplatin model; class evidence for the related GHS-R1a agonist anamorelin in humans does not transfer to ipamorelin.

Lu et al. (2024) [lu2024] demonstrated that anamorelin and ipamorelin attenuated cisplatin-induced weight loss in ferrets, with anamorelin also exhibiting central anti-emetic effects. The orally bioavailable GHS-R1a agonist anamorelin has been studied in human cancer cachexia (and authorized for that indication in some jurisdictions outside the United States); ipamorelin has not been studied in human cancer cachexia and the class data do not transfer.

Anti-aging / body composition / wellness use (unregulated) **EMERGING**

Widely promoted by anti-aging and wellness clinics outside the regulated 503A pathway. No FDA approval, no controlled clinical evidence in healthy adults, and on FDA's Category 2 list as a bulk substance ineligible for 503A compounding.

Evidence should be interpreted in context for ipamorelin. Any patient-specific request requires prescriber rationale and pharmacy review; availability is determined case by case.

⚠️ Compounded Ipamorelin (503A)

Physicians may submit patient-specific prescription requests for pharmacy review. For ipamorelin, certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case and may depend on patient-specific documentation, ingredient status, source qualification, formulation feasibility, state requirements, and pharmacist judgment. The review starts with the evidence constraint: The evidence base for ipamorelin



includes small human pharmacology studies and preclinical work, but no FDA-approved indication. Its selectivity claims do not remove the need for patient-specific rationale, route review, and pharmacist judgment.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. This ingredient is part of an evolving FDA review process for peptide-related bulk substances used in compounding. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For ipamorelin, RonanRx ties that monitoring to the evidence limits described above and to any patient-specific documentation submitted by the prescriber.

Valid patient-specific prescription required. Supporting clinical rationale may be requested. Compounded medications are not FDA-approved. No consumer self-ordering, no office stock, no bulk dispensing. Requests for ipamorelin are reviewed before any preparation is made or released. The regulated path for ipamorelin is not a consumer stack or clinic menu. A physician may submit a prescription request, and the pharmacy decides case by case whether it can be prepared and dispensed.

⊗ Ipamorelin Formulations and Routes

Form	Concentration	Description
Investigational injectable (historical)	—	Used as an intravenous and subcutaneous solution in published phase 1 and phase 2 studies [gobburu1999, beck2014]. No commercial pharmaceutical formulation exists; clinical development was discontinued.
Unregulated bulk powder / reconstituted injection (not from RonanRx)	—	Widely available from online research-chemical sellers and anti-aging clinics outside the 503A regulated pathway. Analytical characterization of seized products documents identity and purity discrepancies [krug2018, gajda2019]. RonanRx does not source, dispense, or endorse these products.

Routes used in published literature: intravenous, subcutaneous.

📄 Ipamorelin Dosing

Route	Population	Range	Duration	Study type
Intravenous (research only)	Healthy adult volunteers (Gobburu 1999 phase 1 PK/PD)	Single IV doses studied in the phase 1 program; dose-dependent GH and IGF-1 responses observed. No therapeutic dose has	Single dose in PK/PD studies	Phase 1 PK/PD in healthy adults



Route	Population	Range	Duration	Study type
		ever been established or approved.		
Intravenous (research only)	Adults undergoing bowel resection (Beck 2014 phase 2 POI trial)	Intravenous ipamorelin administered per the phase 2 trial protocol; primary efficacy endpoint not met. No approved therapeutic dose exists for any indication.	Perioperative dosing window in the phase 2 trial	Phase 2 randomized placebo-controlled trial

No FDA-approved labeled dose exists for ipamorelin. The only published human dosing data are from the phase 1 PK/PD program [gobburu1999] and the phase 2 postoperative ileus trial [beck2014]. The phase 2 trial did not meet its primary endpoint, and clinical development was discontinued before any larger phase 3 dose-finding program.

RonanRx does not publish a consumer dosing schedule for ipamorelin. Any request requires a valid patient-specific prescription, supporting clinical rationale, and pharmacist review. Route, strength, dosing interval, monitoring expectations, and dispensing quantity would be determined case by case from the prescriber's documentation and pharmacy feasibility review.

🛡️ Ipamorelin Safety

The published safety record for ipamorelin in humans is limited to the phase 1 PK/PD studies and the single phase 2 postoperative ileus trial. Gobburu et al. (1999)² reported single-dose intravenous administration was tolerated in healthy adult volunteers with no serious adverse events documented in the published report²¹. Beck et al. (2014)¹⁰ reported the safety profile of intravenous ipamorelin in 114 bowel-resection patients as comparable to placebo, though the trial did not meet its primary efficacy endpoint and the dataset is the limit of the controlled clinical safety record for this molecule¹⁷. There are no published long-term human safety data, no chronic-dosing pharmacovigilance data, no published carcinogenicity assessment in humans, and no published immunogenicity data.

Class-level safety considerations for chronic GHS-R1a agonism are extrapolated from the broader GH-releasing peptide and growth-hormone-axis literature: GH/IGF-1 elevation has known associations with insulin resistance, fluid retention, carpal tunnel symptoms, arthralgia, and (in the recombinant human GH literature) theoretical concerns regarding promotion of pre-existing malignancy. Johansen et al. (2003)⁶ specifically demonstrated downstream GH receptor resistance with chronic GHS-R1a agonism in diabetic mice¹⁴. Adeghate and Ponery (2004)⁷ demonstrated a direct islet effect on insulin release that has not been characterized in humans. None of these class-level signals has been formally evaluated for ipamorelin in any human controlled trial.



Unregulated-supply-chain safety is a separate question. Analytical characterization of seized black-market growth-hormone-releasing peptide products ¹¹¹² has documented identity, dose, and purity discrepancies including misidentified peptides, contamination with related secretagogues, and labels that do not match analytical content ¹⁹. Practitioner-facing reviews catalog these supply-chain risks specifically for the unregulated peptide market in which ipamorelin is widely sold ¹⁸²⁰.

Anti-doping status. Ipamorelin is on the WADA Prohibited List at all times under section S2 ²⁴. Athletes subject to testing should not use ipamorelin regardless of source.

Contraindications

Honest gap. No FDA-approved label exists for ipamorelin and no formal contraindications have been established in peer-reviewed clinical literature. Class-level cautions applicable to growth hormone secretagogues (active malignancy, severe insulin resistance or uncontrolled diabetes, pregnancy and lactation, pediatric use outside dedicated trials) are noted in safety_overview but are extrapolations, not labeled contraindications.

Searched: PubMed, FDA Drugs, WADA on 2026-05-11 · terms *ipamorelin contraindications; NNC 26-0161 contraindications; ghrelin agonist contraindications.*

Drug interactions

Honest gap. No FDA-approved label and no formal drug-interaction studies have been published for ipamorelin. As a small peptide cleared by proteolytic catabolism rather than CYP-mediated metabolism, clinically significant CYP-based drug-drug interactions are not anticipated, but no controlled DDI program has been performed.

Searched: PubMed, FDA Drugs, DailyMed on 2026-05-11 · terms *ipamorelin drug interactions; ipamorelin CYP; ipamorelin co-administration.*

Adverse events

Adverse-event data for ipamorelin in humans are limited to the published phase 1 PK/PD program ² and the phase 2 postoperative ileus trial ¹⁰. Beck et al. reported intravenous ipamorelin was generally tolerated in 114 bowel-resection patients with an AE profile comparable to placebo, in the context of a trial that did not meet its primary efficacy endpoint. Single-dose PK/PD studies in healthy adult volunteers reported no serious adverse events.

There is no published large-population safety dataset, no chronic-dosing pharmacovigilance data, and no published immunogenicity analysis. Adverse events reported by patients using unregulated supply-chain ipamorelin do not enter formal pharmacovigilance systems for a non-approved product; the analytical literature on seized black-market peptides ¹¹¹² documents identity and dose discrepancies that confound any attempt to attribute symptoms to a labeled dose of ipamorelin.



↗ Monitoring Ipamorelin Therapy

No RonanRx-specific monitoring protocol has been established for ipamorelin. If a patient-specific prescription is submitted, supporting clinical rationale may be requested, and monitoring expectations would be reviewed case by case against the published evidence, route, sterile or nonsterile status, concomitant therapies, and patient risk factors.

⚖ Ipamorelin in Special Populations

⚖ Ipamorelin Evidence Quality

The evidence base for ipamorelin is small and stable. Preclinical: the original Raun (1998) characterization [raun1998] established the selectivity profile in rats and pigs; mechanistic work through the 2000s expanded the rodent characterization across bone, somatotroph, GH-axis, and islet effects [andersen2001; jimenez2002]. Preclinical translational work for postoperative ileus [venkova2009, greenwood2012] and visceral nociception [mohammadi2020] continued through the 2010s. Recent preclinical work in ferrets for chemotherapy-induced cachexia [lu2024] reflects continued mechanistic interest in the ghrelin-agonist class, though for ipamorelin specifically the clinical program ended a decade earlier [krug2018; gajda2019].

Human: only the phase 1 PK/PD study [gobburu1999] [gobburu1999] in healthy adult volunteers and the phase 2 postoperative ileus trial [beck2014] [beck2014] in 114 bowel-resection patients have been published in peer review. The phase 2 trial did not meet its primary endpoint; no larger trial was performed and clinical development was discontinued. There is no phase 3 program, no long-term safety dataset, no immunogenicity data, no chronic-dosing pharmacovigilance data, no body-composition trial in healthy adults, no cachexia trial, and no diagnostic-product development [mendias2026; mayfield2026; rahman2026].

Regulatory: ipamorelin has never received FDA or EMA marketing authorization. FDA has placed ipamorelin on its Category 2 list of bulk drug substances nominated for 503A compounding, substances with significant safety concerns that remain under FDA's significant-safety-risk framework [fda_503a_interim_policy]. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case. Ipamorelin is on the WADA Prohibited List at all times [wada_prohibited_list_2025] [coutinho2026; mavrych2026]. The evidence base for the unregulated wellness-clinic use of ipamorelin (typically in combination with CJC-1295) is anecdotal, no controlled trials in healthy adults, and the supply chain itself is documented as carrying identity and purity risk [johansen2003; adeghate2004; ahnfelt2001].



📄 Major Ipamorelin Clinical Studies

Study	Design	Participants	Duration	Finding
Raun et al. (1998, European Journal of Endocrinology), Discovery and characterization	Preclinical pharmacology in rats and swine: receptor binding, in vivo GH-release potency, and cross-axis hormone selectivity (prolactin, ACTH, cortisol, FSH, LH)	—	Single-dose and short-course preclinical	Ipamorelin (NNC 26-0161) is the first selective growth hormone secretagogue, releases GH in pigs and rats without significant elevation of prolactin, ACTH, cortisol, FSH, or LH at GH-releasing doses [raun1998]
Gobburu et al. (1999, Pharmaceutical Research), Phase 1 PK/PD in human volunteers	Phase 1 randomized clinical trial of intravenous ipamorelin PK and GH/IGF-1 PD in healthy adult volunteers	—	—	Plasma half-life approximately 2 hours; dose-dependent GH peak and downstream IGF-1 elevation; selectivity profile in humans consistent with the Raun 1998 preclinical characterization [gobburu1999]
Andersen et al. (2001, Growth Hormone & IGF Research), Glucocorticoid-induced bone loss in rats	Preclinical: chronic ipamorelin in adult rats receiving glucocorticoids; bone-formation endpoints	—	—	Ipamorelin partially counteracted glucocorticoid-induced reduction in bone formation; signal never tested in a human controlled trial [andersen2001]
Ahnfelt-Rønne et al. (2001, Endocrine), Mechanism: direct GHS-R1a engagement vs. ghrelin secretagogue action	Preclinical mechanistic study testing whether GHRPs (including ipamorelin) act as ghrelin secretagogues	—	—	Supported direct GHS-R1a agonism rather than ghrelin-mediated indirect action as the primary mechanism for ipamorelin [ahnfelt2001]
Jiménez-Reina et al. (2002, Histology and Histopathology),	Preclinical: chronic ipamorelin in young female rats; in vitro	—	—	Characterized somatotroph adaptation under chronic



Study	Design	Participants	Duration	Finding
Chronic treatment somatotroph response	somatotroph responsiveness			GHS-R1a agonism in rodents [jimenez2002]
Johansen et al. (2003, Experimental Diabesity Research), GH/IGF-1 axis in diabetic mice	Preclinical: ipamorelin in streptozotocin-diabetic mice; GH and GH receptor signaling endpoints	—	—	GH hypersecretion with downstream GH receptor resistance under chronic GHS-R1a agonism in the diabetic state [johansen2003]
Adeghate and Ponery (2004, Neuro Endocrinology Letters), Pancreatic islet insulin release	Preclinical: isolated rat pancreatic islets from normal and diabetic animals; insulin secretion in response to ipamorelin	—	—	Direct insulin-releasing action of ipamorelin on islets; not characterized in humans [adeghate2004]
Venkova et al. (2009, J Pharmacol Exp Ther), Rodent postoperative ileus model	Preclinical: rodent model of postoperative ileus; ipamorelin prokinetic activity	—	—	Ipamorelin accelerated GI transit recovery in a rodent POI model, the foundation for the subsequent phase 2 human trial [venkova2009]
Greenwood-Van Meerveld et al. (2012, J Exp Pharmacol), Rodent gastric dysmotility in POI	Preclinical: gastric dysmotility endpoint in rodent POI model	—	—	Ipamorelin restored gastric motility in the rodent POI model, consistent with the Venkova preclinical signal [greenwood2012]
Beck et al. (2014, Int J Colorectal Dis), Phase 2 POI trial	Phase 2 randomized, placebo-controlled, proof-of-concept trial of intravenous ipamorelin in adults undergoing open or laparoscopic bowel resection	114	Perioperative dosing window	Primary efficacy endpoint not met. Safety profile comparable to placebo. Clinical development of ipamorelin was subsequently discontinued [beck2014].
Mohammadi et al. (2020, J Exp Pharmacol), Visceral and somatic nociception	Preclinical: visceral and somatic nociception endpoints in rodent models with	—	—	Attenuation of visceral and somatic nociception with ghrelin-receptor agonism; mechanistic extension of the



Study	Design	Participants	Duration	Finding
	ghrelin mimetics including ipamorelin			GI literature [mohammadi2020]
Lu et al. (2024, Physiology & Behavior), Cisplatin-induced cachexia in ferrets	Preclinical: ferret model of cisplatin-induced weight loss; anamorelin and ipamorelin	—	—	Both anamorelin and ipamorelin inhibited cisplatin-induced weight loss in ferrets; anamorelin additionally showed central anti-emetic activity [lu2024]
Krug et al. (2018, Growth Hormone & IGF Research), Black-market product analysis	Analytical characterization of seized growth-hormone-releasing peptide products from the unregulated supply chain	—	—	Documented identity, purity, and labeling discrepancies in unregulated GHRP products including ipamorelin-labeled material [krug2018]
Gajda et al. (2019, Drug Testing and Analysis), Seized doping material	Analytical characterization of glycine-modified GH secretagogues identified in seized doping material	—	—	Identified modified and adulterated growth hormone secretagogues in the unregulated supply chain, reinforcing supply-chain risk for ipamorelin-class products [gajda2019]

⚠ Ipamorelin Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

The only published human PK data for ipamorelin are from Gobburu et al. (1999) [gobburu1999], a phase 1 PK/PD study in healthy adult volunteers receiving intravenous ipamorelin. Plasma half-life was approximately 2 hours, distribution volume was approximately one body-water volume, and clearance was rapid consistent with a small peptide cleared by proteolytic catabolism. No oral bioavailability data have been published. No subcutaneous PK in human disease populations has been published. No population PK analysis exists.

Class-level expectation. Ipamorelin is a 5-amino-acid synthetic peptide with no fatty-acid modification or albumin-binding moiety, in contrast to long-acting peptides such as tirzepatide or semaglutide. The short plasma half-life is consistent with its small size. There are no published data on chronic-dosing accumulation, steady-state PK, or any covariate effects (age, weight, sex, renal or hepatic function).



Pharmacodynamics

Pharmacodynamic effects of ipamorelin in published human studies are dose-dependent serum GH peak with downstream IGF-1 elevation over the dosing interval [gobburu1999]. The selectivity profile (lack of prolactin, ACTH, cortisol, FSH, or LH elevation at GH-releasing doses) was established in the rat and swine work of Raun et al. (1998) [raun1998] and was consistent with the human phase 1 PK/PD characterization.

Pharmacodynamic effects on downstream growth-hormone-axis endpoints (body composition, bone formation, insulin sensitivity) have not been characterized in human controlled trials. Preclinical work supports an osteoanabolic signal in glucocorticoid-treated rats [andersen2001], direct islet insulin release in rats [adehgate2004], and chronic-treatment somatotroph adaptation [jimenez2002]. None of these has been replicated or tested in a human controlled trial.

↕ Comparing Ipamorelin Formulations

There is no manufactured ipamorelin product to compare against. Within the GHS-R1a agonist class, the orally bioavailable agonist anamorelin has been approved in some jurisdictions outside the United States (Japan: Adlumiz, for cancer cachexia) and has a separate clinical evidence base that does not transfer to ipamorelin. The peptidic GHS-R1a agonists hexarelin, GHRP-6, and GHRP-2 share the class mechanism but lack ipamorelin's pituitary-selectivity profile and are similarly not FDA-approved.

Within the growth-hormone-axis pharmacology landscape, the FDA-approved tesamorelin (Egrifta) is a GHRH analog, a separate mechanism, with an FDA labeled use in HIV-associated lipodystrophy. Sermorelin is a GHRH(1-29) analog formerly authorized by FDA for pediatric GH deficiency. These are not interchangeable with ipamorelin in mechanism, evidence, or regulatory status.

🔒 Ipamorelin Storage and Handling

If a ipamorelin preparation is approved after pharmacy review, RonanRx applies source documentation, formulation records, lot traceability, release checks, and storage controls appropriate to the actual dosage form. Research-use vial storage practices do not substitute for pharmacy-assigned storage, beyond-use dating, sterility controls when applicable, or recallable batch records.

🏪 Ipamorelin Compounding & Operations

503A compounding

Physicians may submit patient-specific prescription requests for pharmacy review. For ipamorelin, certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case and may depend on patient-specific



documentation, ingredient status, source qualification, formulation feasibility, state requirements, and pharmacist judgment. The review starts with the evidence constraint: The evidence base for ipamorelin includes small human pharmacology studies and preclinical work, but no FDA-approved indication. Its selectivity claims do not remove the need for patient-specific rationale, route review, and pharmacist judgment.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. This ingredient is part of an evolving FDA review process for peptide-related bulk substances used in compounding. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For ipamorelin, RonanRx ties that monitoring to the evidence limits described above and to any patient-specific documentation submitted by the prescriber.

Valid patient-specific prescription required. Supporting clinical rationale may be requested. Compounded medications are not FDA-approved. No consumer self-ordering, no office stock, no bulk dispensing. Requests for ipamorelin are reviewed before any preparation is made or released. The regulated path for ipamorelin is not a consumer stack or clinic menu. A physician may submit a prescription request, and the pharmacy decides case by case whether it can be prepared and dispensed.

Pharmacist review

For ipamorelin, the pharmacist review starts before any preparation is made. Valid patient-specific prescription required. Supporting clinical rationale may be requested. The pharmacist reviews ingredient status, sourcing, formulation feasibility, state requirements, patient-specific documentation, and whether dispensing is appropriate case by case.

Quality and traceability

If a ipamorelin preparation is approved after pharmacy review, RonanRx applies source documentation, formulation records, lot traceability, release checks, and storage controls appropriate to the actual dosage form. Research-use vial storage practices do not substitute for pharmacy-assigned storage, beyond-use dating, sterility controls when applicable, or recallable batch records. The patient-specific framework and quality controls are documented in the cited compounding references [fda503a; usp_795; usp_797].

Cold chain

If a ipamorelin preparation is approved after pharmacy review, RonanRx applies source documentation, formulation records, lot traceability, release checks, and storage controls appropriate to the actual dosage form. Research-use vial storage practices do not substitute for pharmacy-assigned storage, beyond-use dating, sterility controls when applicable, or recallable batch records.



🗨 Frequently Asked Questions About Ipamorelin

Can physicians request ipamorelin through RonanRx?

Physicians may submit patient-specific prescription requests for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case. Compounded medications are not FDA-approved, and no consumer self-ordering, office stock, or bulk dispensing is offered.

Is ipamorelin FDA-approved for any indication?

No. Ipamorelin has never received FDA approval for any indication. The only published clinical trial, a phase 2 randomized study in postoperative ileus after bowel resection, did not meet its primary efficacy endpoint, and clinical development was discontinued [beck2014].

Why is it sold by anti-aging and wellness clinics if it is not FDA-approved?

Ipamorelin is widely marketed by unregulated anti-aging and wellness clinics, online research-chemical sellers, and the unregulated peptide market. These channels operate outside the 503A regulated pharmacy pathway and outside FDA oversight of finished pharmaceutical products. Analytical characterization of seized black-market peptide products has documented identity, dose, and purity discrepancies [gajda2019]. RonanRx flags this market honestly: the existence of an unregulated supply does not change the substance's FDA regulatory status, and the pharmacy does not participate in that supply chain [krug2018; fda_503a_interim_policy].

What does 'selective' mean for ipamorelin?

In the original Raun (1998) preclinical characterization, ipamorelin released growth hormone in pigs and rats without significantly elevating prolactin, ACTH, cortisol, FSH, or LH at GH-releasing doses [raun1998]. Earlier growth-hormone-releasing peptides (GHRP-6, GHRP-2, hexarelin) cross-activated these other pituitary axes. Selectivity refers specifically to that pituitary-axis profile observed in those preclinical studies.

What clinical evidence exists in humans?

Two published peer-reviewed human studies: Gobburu (1999) phase 1 PK/PD in healthy adult volunteers, and Beck (2014) phase 2 randomized placebo-controlled trial in 114 adults undergoing bowel resection for postoperative ileus [gobburu1999; beck2014]. The phase 2 trial did not meet its primary endpoint. There is no phase 3 program, no long-term safety dataset, and no controlled trial in body composition, anti-aging, or any other commonly promoted use.



Is ipamorelin allowed in sport?

No. Ipamorelin is on the World Anti-Doping Agency Prohibited List at all times under section S2 (peptide hormones, growth factors, related substances and mimetics, growth hormone secretagogues) [wada_prohibited_list_2025]. Athletes subject to anti-doping testing should not use ipamorelin regardless of source.

Can physicians request ipamorelin through RonanRx?

Physicians may submit patient-specific prescription requests for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case. Compounded medications are not FDA-approved, and no consumer self-ordering, office stock, or bulk dispensing is offered.

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How to Access Ipamorelin

Compounded Ipamorelin 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 Ipamorelin, 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)

