RonanRx
PERSONALIZED MEDICINE

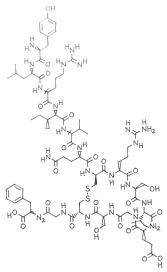
CLINICAL MONOGRAPH · GROWTH-HORMONE AXIS (UNDER FDA REVIEW)

AOD-9604

Growth-hormone fragment with physician-request review

AOD-9604 is a short synthetic peptide that was designed to copy a small piece (residues 177, 191) of human growth hormone, the piece that animal studies suggested could help burn fat [ng2000a]. The Australian biotech Metabolic Pharmaceuticals developed AOD-9604 in the late 1990s and 2000s as a candidate obesity drug [wilding2004]. The hope was that the fragment would retain the fat-burning effects of growth hormone without raising blood sugar or causing growth-hormone-like side effects [heffernan2001a; heffernan2001b].

AOD-9604 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

AOD-9604 is a synthetic 16-amino-acid analogue of the C-terminal lipolytic domain of human growth hormone (hGH 177, 191), originally characterized in rodent obesity models by the University of Melbourne / Monash group and developed by Metabolic Pharmaceuticals Ltd as candidate LY3298176-era obesity therapeutic [fda503a] [wilding2004; jensen2006]. Preclinical rodent work reported reproducible increases in fat oxidation, reductions in adipose mass, and absence of the hyperglycemic / IGF-1-elevating effects characteristic of intact hGH [heffernan2001b]. Investigational reviews from the era catalog AOD-9604 alongside other peptide and small-molecule anti-obesity candidates that were in clinical development in the 2000s [ogru2000].

AOD-9604 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 AOD-9604

The evidence base for AOD-9604 includes early obesity-focused development and growth-hormone-fragment pharmacology, but it did not become an FDA-approved metabolic drug. Published evidence does not support broad consumer weight-loss claims.

Physicians may submit patient-specific prescription requests for AOD-9604 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.

A patient-specific prescription request is not a weight-loss product listing. It must be tied to clinician documentation, pharmacy review, ingredient sourcing, and formulation feasibility before any dispensing decision.

Quick Facts About AOD-9604

Category: Synthetic 16-amino-acid analogue of the C-terminal fragment (residues 177, 191) of human growth hormone (hGH), engineered to retain lipolytic activity without GH-like effects on linear growth or IGF-1

Active ingredient: AOD-9604 (also written AOD9604), a tyrosylated 16-residue peptide derived from the human growth hormone 177, 191 lipolytic domain

FDA-approved branded forms: None. AOD-9604 has no FDA-approved indication or branded product in the United States.

Route: Subcutaneous injection in clinical trials; oral and sublingual routes studied preclinically with limited bioavailability data

Evidence posture: Preclinical rodent studies (Heffernan, Ng) characterize lipolytic and fat-oxidation effects; one phase 2b obesity program in adults run by Metabolic Pharmaceuticals (Australia) reported failure to meet the primary weight-loss endpoint and human obesity development was discontinued

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

Compounded under: Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case.

Australian regulatory note: AOD-9604 was at one point notified to the Australian TGA as an ingredient considered acceptable for use in cosmetic and dietary contexts; this notification is jurisdiction-specific to Australia and does not extend to US drug status

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Physicians may submit patient-specific prescription requests for AOD-9604 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 AOD-9604?

AOD-9604 is a synthetic peptide corresponding to a modified form of the C-terminal sequence (residues 177, 191) of human growth hormone, with an additional N-terminal tyrosine residue. Native hGH is a 191-amino-acid protein with multiple functional domains; the 177, 191 segment was identified in the 1990s by Ng, Heffernan, and colleagues at Monash University and the University of Melbourne as carrying the lipolytic / fat-oxidation activity of the parent hormone in rodent models without the somatogenic (growth-promoting) and glycemic effects mediated through the intact hGH receptor [ng2000a, heffernan2000].

AOD-9604 was developed under that hypothesis by Metabolic Pharmaceuticals Ltd, a Melbourne-based biotechnology company spun out from Monash University. The molecule was advanced into preclinical and clinical development as a candidate anti-obesity peptide. Subsequent structural and conformational work [ogru2000] characterized cyclized and modified analogues of the same C-terminal domain. The compound is most commonly described in the literature as 'AOD-9604', 'AOD9604', or 'tyr-hGH(177-191)'.

There is no FDA-approved finished drug product containing AOD-9604. In the published clinical-development era, investigational supply was prepared as a sterile peptide solution for subcutaneous injection [wilding2004]; oral and sublingual administration was also explored preclinically with limited oral bioavailability data [heffernan2000].

How AOD-9604 Works

The mechanistic rationale for AOD-9604 originates from work characterizing the C-terminal region of human growth hormone as a discrete lipolytic domain. Ng and colleagues reported that synthetic peptides derived from residues 177, 191 of hGH stimulate lipolysis and inhibit lipogenesis in adipocytes and adipose tissue from obese rodents without engaging the intact growth-hormone receptor pathway that mediates linear growth, IGF-1 elevation, and glucose intolerance [ng2000a, ng2000b]. The compound's putative selectivity for the lipolytic phenotype over the somatogenic phenotype was the central design hypothesis.

In rodent studies, AOD-9604 increases whole-body fat oxidation and reduces adipose mass in genetically obese (ob/ob) and diet-induced obese mice [heffernan2001a, heffernan2001b]. Heffernan et al. (2001) used β3-adrenergic receptor knockout mice to argue that the lipolytic effect of AOD-9604 in mice did not strictly depend on β3-AR signaling, distinguishing the proposed mechanism from classical sympathomimetic lipolytics. Oral administration of a synthetic fragment of human growth hormone in the same model system [heffernan2000] reported reductions in adiposity, although oral bioavailability of peptide drugs is generally poor and the translational relevance of the oral preclinical signal to human subcutaneous dosing remained uncertain.

Importantly, the rodent mechanistic data have not been replicated in adequately powered human pharmacology studies in the peer-reviewed literature. Investigational-drug reviews from the development era [wilding2004, jensen2006, halford2006] described the mechanistic rationale and the early clinical pharmacology, but no published human pharmacodynamic study demonstrates a sustained, clinically meaningful increase in fat oxidation or reduction in adipose mass that matches the rodent phenotype.

Biological Role of AOD-9604

Human growth hormone (hGH) is a 191-amino-acid pituitary peptide that signals through the growth-hormone receptor to drive longitudinal growth, hepatic IGF-1 production, and a set of metabolic effects including lipolysis, increased lean mass, and (at supraphysiologic exposure) insulin resistance [wilding2004]. The 177, 191 C-terminal segment was proposed in the 1990s and 2000s as a region carrying a discrete lipolytic phenotype distinct from the somatogenic effects of intact hGH [ng2000a, heffernan2000].

AOD-9604 is a synthetic analogue of this region, designed to retain the proposed adipose-tissue effect while sparing the systemic GH/IGF-1 axis. The biological framing is therefore narrower than for incretin-axis peptides or melanocortin-axis peptides: AOD-9604 is best understood as a candidate selective lipolytic agent rather than as a hormone replacement or a broad metabolic peptide [wilding2004]. The clinical translational track has not validated the rodent biology in adequately powered human trials.

Detailed Mechanism of AOD-9604

The 177, 191 region of human growth hormone has been studied as a putative lipolytic fragment since the 1990s. Ogru et al. (2000) used solution-phase conformational analysis to characterize a cyclic anti-obesity peptide derived from the C-terminal domain of hGH, supporting the structural plausibility of a fold-stable short peptide retaining lipolytic activity [ogru2000]. Ng et al. (2000) reported that an earlier related fragment (AOD9401) exerted molecular and cellular actions on lipid metabolism in Zucker fatty rats [ng2000b], and the parallel study on AOD-9604 itself [ng2000a] reported lipolytic and anti-lipogenic activity in obese-rodent adipose tissue. Heffernan and colleagues consolidated the pharmacology in vivo with reports of chronic-treatment fat-oxidation and weight-reduction effects in obese and β3-AR knockout mice [heffernan2001a, heffernan2001b] and an earlier study of an oral synthetic fragment of hGH [heffernan2000].

The downstream signaling pathways have not been fully resolved. Multiple authors have proposed a lipolytic action mediated independently of the canonical hGH receptor and partially independent of β3-adrenergic receptor signaling [heffernan2001a]. No single high-affinity receptor for AOD-9604 has been identified, and the molecular pharmacology remains poorly characterized relative to the depth of mechanistic work available for clinically successful incretin-axis peptides.

Doping-control analytical work has characterized the chemical structure, in vitro metabolism, and detectability of AOD-9604 in human urine and seized illicit-supply preparations [cox2015]. These analyses confirm that AOD-9604 does not cross-react with the WADA hGH isoform immunoassay [orlovius2013], consistent with its short-peptide structure and distinct antigenicity from intact hGH. Vanhee et al. (2014) reported analytical characterization of unknown peptide preparations seized by Belgian authorities and identified AOD-9604 in the illicit supply chain, underscoring the distinction between regulated investigational supply and unregulated international peptide trade [vanhee2014; thevis2014].

AOD-9604 Research History

AOD-9604 was developed by Metabolic Pharmaceuticals Ltd, a Melbourne biotechnology company founded on intellectual property from Monash University and the University of Melbourne characterizing the lipolytic domain of human growth hormone [ng2000a; ng2000b; heffernan2000]. The discovery work was led by F.M. Ng and the in vivo pharmacology by M.A. Heffernan and colleagues; foundational peer-reviewed reports appeared in 2000 and 2001 [heffernan2001a].

Clinical development through the 2000s targeted adult obesity [halford2006; zieba2007]. Investigational-drug reviews from 2004, 2007 catalog AOD-9604 alongside other peptide and small-molecule anti-obesity candidates of the era [ogru2000]. Khan et al. (2012) included AOD-9604 in a broader review of medical management of obesity, summarizing the development status as inactive in obesity [khan2012]. The pivotal phase 2b weight-loss study run by Metabolic Pharmaceuticals failed to meet its primary endpoint for clinically meaningful weight loss versus placebo, and the company announced in 2007 that it was discontinuing obesity development [heffernan2001b; jensen2006]. The trial was not published in the indexed peer-reviewed literature; the development outcome is described in the investigational-drug reviews cited above [wilding2004, khan2012]. No subsequent phase 3 obesity program has been undertaken [cox2015].

After the obesity program closed, two distinct strands of work appeared. Kwon and Park (2015) reported a preclinical study of intra-articular AOD-9604 with and without hyaluronic acid in a rabbit osteoarthritis model [kwon2015], suggesting a potential cartilage-protective signal in that small-animal study. Separately, the sports anti-doping research community has continued analytical characterization of AOD-9604 because of its appearance in illicit performance-enhancing peptide preparations [vanhee2014; thevis2014]. There is no recent peer-reviewed human-efficacy trial program for AOD-9604 in any indication [orlovius2013].

AOD-9604 Timeline

2000 • Ng et al [ng2000a]. (Hormone Research), Metabolic studies of a synthetic lipolytic domain (AOD9604) of human growth hormone in obese rodent adipose tissue

2000 • Ng et al [ng2000b]. (J Mol Endocrinol), Molecular and cellular actions of the related structural domain AOD9401 in Zucker fatty rats

2000 • Heffernan et al [heffernan2000]. (Am J Physiol Endocrinol Metab), Oral administration of a synthetic hGH C-terminal fragment in rodents

2000 • Ogru et al [ogru2000]. (J Peptide Res), Conformational and biological analysis of a cyclic anti-obesity peptide from the hGH C-terminal domain

2001 • Heffernan et al [heffernan2001b]. (Int J Obes), Chronic hGH or modified C-terminal fragment increases fat oxidation and reduces weight in obese mice

2001 • Heffernan et al [heffernan2001a]. (Endocrinology), AOD-9604 chronic treatment in obese and β3-AR knockout mice; weight and lipid-metabolism effects partially independent of β3-AR signaling

2004 • Wilding (Curr Opin Investig Drugs), Investigational-drug review of AOD-9604 (Metabolic Pharmaceuticals) [wilding2004]

2006 • Halford (Curr Opin Investig Drugs) and Jensen (Obesity), investigational-drug landscape reviews covering AOD-9604 alongside other clinical-stage anti-obesity candidates [halford2006; jensen2006]

2007 • Metabolic Pharmaceuticals announces failure of the AOD-9604 phase 2b adult obesity study to meet its primary weight-loss endpoint; obesity development is discontinued [wilding2004; khan2012; zieba2007]. Zieba (Postepy Hig Med Dosw) reviews the broader anti-obesity pipeline of the era including AOD-9604.

2012 • Khan et al [khan2012]. (Recent Pat Endocr Metab Immune Drug Discov), review of medical management of obesity catalogs AOD-9604 development status as inactive in obesity

2013 • Orlovius et al [orlovius2013]. (Drug Test Anal), AOD-9604 does not cross-react with the WADA hGH isoform immunoassay; analytical-detection groundwork

2014 • Vanhee et al. (Drug Test Anal), AOD-9604 identified in unknown pharmaceutical preparations seized by Belgian authorities; Thevis et al [vanhee2014; thevis2014]. review analytical approaches to detection of emerging non-approved drugs in doping controls

2015 • Cox et al [cox2015]. (Drug Test Anal), detection and in vitro metabolism of AOD-9604 in support of sports doping controls

2015 • Kwon and Park (Ann Clin Lab Sci), preclinical rabbit osteoarthritis model: intra-articular AOD-9604 with or without hyaluronic acid suggests cartilage-related signal in small-animal study [kwon2015]

2019 • FDA Pharmacy Compounding Advisory Committee proceedings and subsequent FDA Category lists place AOD-9604 on the 503A bulk drug substances Category 2 list, nominated substances under agency review whose use in 503A compounding raises significant safety risks pending evaluation [fda_bulks_category2]

Clinical Contexts for AOD-9604

Adult obesity / weight management EMERGING

Investigated in a phase 2b weight-loss trial that did not meet its primary endpoint; clinical development for obesity discontinued. AOD-9604 has no FDA approval for weight management.

Metabolic Pharmaceuticals advanced AOD-9604 through phase 1 and phase 2 clinical development for adult obesity through the 2000s on the basis of rodent lipolytic and fat-oxidation data [ng2000a, heffernan2001a, heffernan2001b]. Investigational-drug-pipeline reviews from the era described the program and dosing strategy [wilding2004, halford2006, jensen2006]. The pivotal phase 2b obesity study did not show a clinically meaningful weight-loss difference versus placebo at the primary endpoint, and Metabolic Pharmaceuticals discontinued the obesity development program in 2007 [khan2012, zieba2007]. The phase 2b trial was not published in the indexed peer-reviewed literature; the program failure is documented in subsequent review articles cataloging the anti-obesity pipeline. No phase 3 obesity development has been undertaken since.

Osteoarthritis (intra-articular) PRECLINICAL

Single rabbit-model preclinical study; no human trials.

Kwon and Park (2015) reported intra-articular AOD-9604, alone or combined with hyaluronic acid, in a rabbit model of knee osteoarthritis [kwon2015]. The study described histologic and imaging signals consistent with reduced cartilage damage in the combined-treatment arm. This is a single small-animal study and has not been followed by human trials; the finding is hypothesis-generating only.

Off-Label Uses of AOD-9604

Anti-doping detection target PRECLINICAL

Not a clinical use. AOD-9604 has appeared in illicit international peptide markets and is monitored by sports anti-doping laboratories.

AOD-9604 has been detected in unknown pharmaceutical preparations seized by national authorities [vanhee2014] and is the subject of analytical-method development for sports doping controls [orlovius2013, cox2015, thevis2014]. These analytical studies do not establish clinical efficacy or a clinical role; they document the substance's presence in unregulated supply chains and its detection chemistry. RonanRx flags this context because the unregulated international peptide market is the principal route by which AOD-9604 reaches end-users today.

FDA-Approved Uses of AOD-9604

AOD-9604 has no FDA-approved indication and no FDA-approved branded finished drug product. It has never received a new drug application (NDA) approval, an abbreviated new drug application (ANDA) approval, a biologics license application (BLA) approval, or an over-the-counter (OTC) monograph listing in the United States. There is no FDA-approved label, no approved patient population, no approved dosing regimen, and no approved manufacturer.

AOD-9604 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.

Compounded AOD-9604 (503A)

Physicians may submit patient-specific prescription requests for pharmacy review. For AOD-9604, 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 AOD-9604 includes early obesity-focused development and growth-hormone-fragment pharmacology, but it did not become an FDA-approved metabolic drug. Published evidence does not support broad consumer weight-loss claims.

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 AOD-9604, 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 AOD-9604 are reviewed before any preparation is made or released. A patient-specific prescription request is not a weight-loss product listing. It must be tied to clinician documentation, pharmacy review, ingredient sourcing, and formulation feasibility before any dispensing decision.

AOD-9604 Formulations and Routes

Form	Concentration	Description
Investigational subcutaneous injection (historical)	Per Metabolic Pharmaceuticals investigational protocols (1990s, 2000s); not commercially supplied	Sterile peptide solution for subcutaneous administration used in phase 1 and phase 2 trials run by Metabolic Pharmaceuticals. No FDA-registered manufactured product exists. No FDA-cleared compounded formulation exists.
Unregulated grey-market preparations	—	AOD-9604 has been identified in pharmaceutical preparations seized by national authorities and in research-grade peptide supply chains [vanhee2014, cox2015]. These preparations are outside any regulated quality system and are not eligible for clinical use; RonanRx does not source, dispense, or counsel on grey-market AOD-9604.

Routes used in published literature: subcutaneous, intramuscular, oral, sublingual.

AOD-9604 Dosing

Route	Population	Range	Duration	Study type
Subcutaneous	Adults with obesity (historical investigational use, Metabolic Pharmaceuticals phase 1/2 program)	Doses described in investigational-drug reviews ranged from approximately 0.25 mg to 1 mg subcutaneously, typically once daily, over weeks of dosing. The phase 2b weight-loss trial did not	Up to 12 weeks in the phase 2b program	Historical investigational dosing, no FDA-approved regimen

Route	Population	Range	Duration	Study type
		meet its primary endpoint, and no labeled dose exists.		
Oral	Preclinical rodent obesity models	Oral synthetic hGH C-terminal fragments were dosed in rodent studies; human oral bioavailability of AOD-9604 has not been characterized in the published peer-reviewed literature	Up to several weeks in rodent studies	Preclinical rodent, does not translate to human dosing

There is no labeled dose for AOD-9604. The Metabolic Pharmaceuticals investigational program used subcutaneous daily dosing in the sub-milligram-to-low-milligram range during phase 1 and phase 2 studies in the 2000s. Because the phase 2b obesity trial did not show a clinically meaningful weight-loss difference versus placebo at the primary endpoint and the obesity program was discontinued, the historical investigational regimens carry no evidence of clinical benefit and should not be reused as a basis for current dosing decisions [khan2012].

Doses described in the unregulated international peptide market (variably reported as 0.25, 1 mg subcutaneously, daily or several times weekly) do not correspond to any FDA-reviewed dosing regimen and are not supported by published human efficacy or safety data. RonanRx does not provide compounded AOD-9604 and does not recommend a dosing regimen for AOD-9604 [wilding2004].

AOD-9604 Safety

The published human safety database for AOD-9604 is limited to the phase 1 and phase 2 investigational program run by Metabolic Pharmaceuticals in the 2000s, the primary trial reports of which were not published in indexed peer-reviewed journals [79]. Investigational-drug reviews from the era describe the development-program tolerability as acceptable at the doses tested, generally without the hyperglycemia, IGF-1 elevation, or fluid-retention adverse-event profile characteristic of intact hGH, but these summaries are secondary descriptions rather than independent safety analyses, and the phase 2b weight-loss study did not yield a positive efficacy signal that would have advanced the molecule into a phase 3 safety database [81110].

There is no published long-term human safety data, no published cardiovascular safety data, no published reproductive or carcinogenicity data, and no FDA safety review. Analytical work has identified AOD-9604 in seized illicit pharmaceutical preparations and in research-grade supply chains; this material is outside any regulated quality system and carries the additional safety considerations typical of unregulated injectable peptides: sterility, endotoxin, identity, and potency cannot be assumed [121315].

The FDA's placement of AOD-9604 on the 503A bulk drug substances Category 2 list [17] signals that the agency has identified significant safety questions about its use in 503A compounding pending agency review. RonanRx treats AOD-9604 as not eligible for compounding during the evolving FDA review process [14].

Contraindications

Honest gap. There is no FDA-approved label for AOD-9604 and no FDA-reviewed list of contraindications, warnings, or precautions. Because there is no FDA-approved indication and AOD-9604 sits on the FDA 503A bulks Category 2 list, RonanRx treats AOD-9604 as not eligible for clinical use, which functions as a categorical contraindication to RonanRx-dispensed use.

Searched: PubMed, FDA Drugs@FDA, DailyMed, FDA 503A bulk drug substances Category 2 list on 2026-05-11 · terms *AOD-9604 OR AOD9604 OR "hGH 177-191", contraindications, warnings, precautions*.

Drug interactions

Honest gap. No published clinically validated drug-drug interaction data are available for AOD-9604. The molecule has not been characterized in dedicated human CYP-substrate or transporter-substrate studies in the peer-reviewed literature. Cox et al. (2015) reported in vitro metabolism work in the context of doping-control assay development [cox2015]; this does not constitute a clinical DDI assessment.

Searched: PubMed, FDA Drugs@FDA, DailyMed on 2026-05-11 · terms *AOD-9604 OR AOD9604 drug interactions, pharmacokinetic interactions, CYP*.

Adverse events

Honest gap. No FDA-reviewed adverse-event analysis exists for AOD-9604. The Metabolic Pharmaceuticals phase 1/2 program tolerability data were summarized in investigational-drug reviews [wilding2004, khan2012] as generally acceptable at the doses tested, but the primary trial reports were not published in the indexed peer-reviewed literature. No published FAERS analysis or post-marketing safety database is available because AOD-9604 has never been a marketed FDA-approved drug. Unregulated international supply [vanhee2014, cox2015] carries the additional risks typical of grey-market injectable peptides, sterility, endotoxin, identity, potency, which cannot be characterized at population level in the absence of a regulated supply chain.

Searched: PubMed, FDA FAERS public dashboard, FDA 503A bulks Category 2 documentation on 2026-05-11 · terms *AOD-9604 OR AOD9604 adverse events, FAERS, postmarketing, injection-site, hypersensitivity*.

Monitoring AOD-9604 Therapy

No RonanRx-specific monitoring protocol has been established for AOD-9604. 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.

AOD-9604 in Special Populations

AOD-9604 Evidence Quality

The evidence base for AOD-9604 is dominated by a small set of preclinical rodent studies from 2000, 2001 that characterize lipolytic and fat-oxidation effects in obese-rodent models and propose a mechanism partially independent of β3-adrenergic receptor signaling [heffernan2001a; orlovius2013]. These studies, conducted by the discovery group and the developer (Metabolic Pharmaceuticals), are supportive of the original lipolytic-fragment hypothesis but have not been independently replicated at scale, and the rodent phenotype has not been recapitulated in adequately powered published human pharmacology studies [ng2000a; heffernan2001b; ogru2000].

Human clinical evidence is restricted to the Metabolic Pharmaceuticals phase 1 and phase 2 development program of the 2000s. The pivotal phase 2b adult-obesity trial did not meet its primary weight-loss endpoint, and Metabolic Pharmaceuticals discontinued obesity development [jensen2006; zieba2007; khan2012]. The phase 2b results are not in the indexed peer-reviewed literature; the development outcome is documented through investigational-drug reviews and pipeline analyses of the era [vanhee2014]. The single post-obesity-program preclinical signal is the rabbit osteoarthritis study by Kwon and Park (2015) [kwon2015], which has not been followed by human trials [ng2000b; heffernan2000].

Analytical doping-control literature characterizes detection chemistry and confirms the presence of AOD-9604 in unregulated supply chains, but is not a clinical-efficacy or safety evidence stream [cox2015; thevis2014]. The overall evidence quality for AOD-9604 in any clinical indication is low: a failed phase 2b obesity primary endpoint, no completed phase 3 program, no FDA approval, and FDA Category 2 status on the 503A bulks list [fda_bulks_category2] [wilding2004; halford2006].

Major AOD-9604 Clinical Studies

Study	Design	Participants	Duration	Finding
Ng et al. (2000, Hormone Research), AOD9604 lipolytic domain	Preclinical adipocyte and adipose-tissue pharmacology study of synthetic hGH 177, 191 fragment (AOD-9604) in obese-rodent tissues	—	—	Reported lipolytic and anti-lipogenic activity in obese-rodent adipose tissue without engagement of the somatogenic hGH-receptor pathway; foundational discovery report for the molecule [ng2000a]
Ng et al. (2000, J Mol Endocrinol), AOD9401 in Zucker fatty rats	Preclinical molecular and cellular pharmacology of the related hGH C-terminal fragment AOD9401	—	—	Characterized lipid-metabolism actions of a structurally related hGH C-terminal fragment in genetically obese rats, supporting the lipolytic-domain hypothesis [ng2000b]
Heffernan et al. (2000, Am J Physiol Endocrinol Metab), Oral hGH C-terminal fragment	Preclinical rodent study of oral administration of a synthetic hGH C-terminal fragment	—	—	Reported reductions in adiposity with oral dosing in rodents; oral bioavailability and translational relevance to human dosing remained uncharacterized [heffernan2000]
Ogru et al. (2000, J Peptide Res), Cyclic anti-obesity peptide conformation	Structural and conformational analysis of cyclized hGH C-terminal-domain peptides	—	—	Characterized the fold and biological activity of cyclic AOD-9604-related peptides; supports the structural rationale for short-peptide retention of lipolytic activity [ogru2000]
Heffernan et al. (2001, Int J Obes), Fat oxidation in obese mice	Preclinical chronic dosing study of intact hGH and modified C-terminal fragment in ob/ob and diet-induced obese mice	—	—	Chronic treatment with hGH or the modified C-terminal fragment increased fat oxidation and reduced body weight in obese mice [heffernan2001b]
Heffernan et al. (2001, Endocrinology), β3-	Preclinical chronic treatment of obese and β3-adrenergic receptor knockout	—	—	Weight and lipid-metabolism effects of AOD-9604 were partially independent of β3-AR signaling, distinguishing the mechanism from

Study	Design	Participants	Duration	Finding
AR knockout mechanism	mice with hGH and AOD-9604			classical sympathomimetic lipolytics [heffernan2001a]
Wilding (2004, Curr Opin Investig Drugs), AOD-9604 development review	Investigational-drug profile of AOD-9604	—	—	Summarized the Metabolic Pharmaceuticals development program, dosing strategy, and early clinical results; this and related reviews are the principal published-literature record of the clinical development history [wilding2004]
Khan et al. (2012, Recent Pat Endocr Metab Immune Drug Discov), Obesity-pipeline review	Narrative review of medical management of obesity, including the historical AOD-9604 development program	—	—	Documented discontinuation of AOD-9604 obesity development after the phase 2b weight-loss trial did not meet its primary endpoint; consistent with the contemporaneous reviews by Wilding (2004), Halford (2006), Jensen (2006), and Zieba (2007) [khan2012; wilding2004; halford2006; jensen2006; zieba2007]
Kwon and Park (2015, Ann Clin Lab Sci), Rabbit osteoarthritis preclinical	Preclinical rabbit knee osteoarthritis model with intra-articular AOD-9604, hyaluronic acid, or combination	—	—	Reported histologic and imaging signals consistent with reduced cartilage damage in the combination arm; hypothesis-generating single small-animal study, no human follow-up [kwon2015]
Cox et al. (2015, Drug Test Anal), Detection and in vitro metabolism	Analytical-chemistry study characterizing AOD-9604 detection methodology and in vitro metabolic profile for sports doping controls	—	—	Established assay parameters and metabolic-fragment patterns enabling detection of AOD-9604 in human urine; complemented by Orlovius et al [cox2015; orlovius2013]. (2013) demonstrating that AOD-9604 does not cross-react with the WADA hGH isoform immunoassay
Vanhee et al. (2014, Drug Test Anal),	Analytical case report on identification of	—	—	Confirmed AOD-9604 presence in illicit injectable peptide

Study	Design	Participants	Duration	Finding
Seized preparations case report	AOD-9604 in unknown pharmaceutical preparations seized by Belgian authorities			preparations sold outside any regulated quality system; representative of the supply chain through which AOD-9604 reaches end-users in the absence of an FDA-approved or 503A-eligible pathway [vanhee2014]

AOD-9604 Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Published human pharmacokinetic data for AOD-9604 are limited. The Metabolic Pharmaceuticals phase 1 program characterized basic PK parameters for subcutaneous administration, but primary PK reports were not published in indexed peer-reviewed journals; the development-era reviews [wilding2004] reference the program at a summary level only. Analytical work for doping control [cox2015] characterized in vitro metabolism of AOD-9604, identifying degradation patterns relevant for urinary detection methodology; this is not equivalent to a clinical PK characterization.

Oral administration of a related synthetic hGH C-terminal fragment was studied in rodents [heffernan2000]; oral peptide bioavailability is generally poor and the rodent oral data do not translate to a human oral dosing regimen. No validated human PK parameters (Cmax, Tmax, AUC, half-life, clearance, volume of distribution, bioavailability by route) appear in the indexed peer-reviewed literature.

Pharmacodynamics

Pharmacodynamic effects described for AOD-9604 in the preclinical literature center on lipolysis and fat oxidation in obese-rodent adipose tissue, with reductions in body fat mass over weeks of chronic dosing [ng2000a, heffernan2001a, heffernan2001b]. The reported absence of hGH-receptor-mediated effects (IGF-1 elevation, fasting hyperglycemia, fluid retention) at active lipolytic doses was the design rationale.

Adequately powered human pharmacodynamic data confirming a sustained, clinically meaningful effect on fat oxidation or adiposity have not been published. The phase 2b adult-obesity trial did not meet its primary weight-loss endpoint, which is the principal published-record human pharmacodynamic readout for the molecule and is interpretable as a negative clinical PD signal at the doses and durations tested [wilding2004, khan2012].

Comparing AOD-9604 Formulations

There is no FDA-approved comparator formulation for AOD-9604. Within the broader hGH-axis space, AOD-9604 is structurally and pharmacologically distinct from FDA-approved recombinant human growth hormone (somatropin) products, which are full-length 191-amino-acid proteins with established GH-receptor pharmacology, and from growth-hormone secretagogues such as the ghrelin-axis peptides. Unlike incretin-axis peptides (semaglutide, tirzepatide), which have completed phase 3 weight-management programs and have FDA-approved branded products, AOD-9604 did not advance beyond phase 2b obesity development [wilding2004; khan2012].

AOD-9604 Storage and Handling

There is no FDA-approved storage labeling for AOD-9604 because there is no FDA-approved product. Historical investigational supply was handled per Metabolic Pharmaceuticals' phase 1/2 trial protocols. RonanRx does not store or dispense AOD-9604.

AOD-9604 Compounding & Operations

503A compounding

Physicians may submit patient-specific prescription requests for pharmacy review. For AOD-9604, 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 AOD-9604 includes early obesity-focused development and growth-hormone-fragment pharmacology, but it did not become an FDA-approved metabolic drug. Published evidence does not support broad consumer weight-loss claims.

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 AOD-9604, 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 AOD-9604 are reviewed before any preparation is made or released. A patient-specific

prescription request is not a weight-loss product listing. It must be tied to clinician documentation, pharmacy review, ingredient sourcing, and formulation feasibility before any dispensing decision.

Pharmacist review

For AOD-9604, 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 AOD-9604 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 [usp_795; usp_797].

Cold chain

If a AOD-9604 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 AOD-9604

Can physicians request AOD-9604 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.

What is AOD-9604?

AOD-9604 is a synthetic 16-amino-acid peptide based on residues 177, 191 of human growth hormone [heffernan2000]. It was designed in the 1990s by the Australian biotechnology company Metabolic Pharmaceuticals as a candidate anti-obesity therapeutic that would retain the lipolytic (fat-burning) effects of growth hormone without the systemic GH/IGF-1 effects [ng2000a; wilding2004].

Did AOD-9604 work for weight loss?

The pivotal phase 2b adult-obesity weight-loss trial run by Metabolic Pharmaceuticals did not meet its primary weight-loss endpoint, and the company discontinued obesity development for AOD-9604 in 2007 [wilding2004; halford2006; jensen2006]. There is no completed phase 3 obesity program [khan2012]. The result of the phase 2b study is documented through subsequent investigational-drug pipeline reviews; the primary trial was not published in the indexed peer-reviewed literature.

Is AOD-9604 FDA-approved?

No. AOD-9604 has no FDA-approved indication or branded product. It has not been the subject of an approved NDA, ANDA, BLA, or OTC monograph. It is on FDA's 503A bulk drug substances Category 2 list, which means the FDA has identified significant safety questions and the substance is not eligible for routine patient-specific compounding under section 503A [fda_bulks_category2; fda503a].

Why is AOD-9604 still discussed if obesity development failed?

Two reasons. First, a single 2015 rabbit-osteoarthritis preclinical study suggested a possible cartilage-protective signal at the intra-articular route, which has occasionally been cited in marketing materials for unregulated peptide suppliers; this is a single small-animal study and has not been followed by human trials [kwon2015]. Second, AOD-9604 is encountered by sports anti-doping laboratories in seized illicit peptide preparations, which has driven analytical-method development [vanhee2014]. Neither line of work establishes a clinical role for AOD-9604 [cox2015; orlovius2013; thevis2014].

Is the Australian TGA listing the same as US approval?

No. Australian regulatory notifications addressing AOD-9604 in cosmetic or dietary ingredient contexts are jurisdiction-specific to Australia and do not represent therapeutic-goods registration as a drug for any indication. They have no bearing on US drug status, which is governed by the FDA [fda_bulks_category2]. AOD-9604 has no FDA approval and is on the FDA 503A bulks Category 2 list [vanhee2014].

What should clinicians do if a patient is already using AOD-9604?

For AOD-9604, physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and supporting clinical rationale may be requested.

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How to Access AOD-9604

Compounded AOD-9604 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 AOD-9604, 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)