Hormonaly ACADEMY

EVIDENCE MONOGRAPH · FOR LICENSED CLINICIANS

Growth Hormone

Somatropin, long-acting analogues and secretagogues — the evidence, the dosing, and the law

A grounded, evidence-graded reference: who truly has GH deficiency and how to prove it, every daily and weekly GH product with its labeled dosing, what oral and injectable secretagogues can and cannot do, and the regulatory and medicolegal map across countries — stated plainly.

First edition · 2026 · revised printing



hGH residues 1–15 of 191 · 22 kDa

Fady Hannah-Shmouni, MD FRCPC
Endocrinologist and biochemical geneticist

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An authoritative reference for licensed clinicians. Educational content and a reference for clinical reasoning — not medical advice for any individual.

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Educational content for licensed clinicians. It is not medical advice for any individual, does not establish a clinician–patient relationship, and does not replace specialist input or formal guidelines. The author and publisher have checked the sources cited, but medicine changes and errors occur; readers must verify drug names, doses, labeled indications and regulatory status against current primary sources before acting. Neither the author nor the publisher accepts liability for loss or harm arising from use of this book.

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How to use this book

How the chapters are built, what the evidence grades mean, and the limits of this reference.

HOW EACH CHAPTER IS BUILT

- A one-line statement of the clinical idea, then focused prose with inline citations numbered per chapter [1].
- Evidence chips mark the kind of data behind a claim: human trials, diagnostic cohorts, regulatory primary sources, or mechanistic studies.
- A letter grade (A to D) rates the strength of evidence for the specific clinical claim — not biological plausibility. Single-domain clinical chapters carry a chapter header badge; multi-tier comparative and statutory chapters assign separate grades per claim in their closing summary chips.
- KEY POINT boxes carry the takeaway; CLINICAL PEARL boxes give bedside tips; SAFETY / CAUTION boxes highlight clinical hazards and supply constraints; METHODS & REPRODUCIBILITY boxes document original quantitative syntheses; figures are schematic unless stated; a References list closes each chapter.
- Eight house quantitative syntheses (MA-1 to MA-5 and STAT-1 to STAT-3) were performed for this monograph from primary trial and registry data: REML random-effects meta-analyses with Hartung–Knapp–Sidik–Jonkman intervals, mixed-effects meta-regression, Bayesian pretest–posttest diagnostic modeling, cross-class body-composition partitioning, observational confounding E-values, and absolute risk-excess (NNH) analyses. They are explicitly labeled, are not externally peer reviewed, and their CSV datasets and R/Python verification scripts accompany this release.

WHAT THE GRADES MEAN

Grade colors match the capsules printed beside claims and chapter headers.

GRADE	MEANING
A	Consistent randomized trials or meta-analyses for the stated indication.
B	A single high-quality trial, lower-quality trials, or strong observational data.
C	Limited data; mechanism plus small, physiological, or uncontrolled studies.

HOW TO USE THIS BOOK · CONTINUED

D — Very low certainty: preclinical, in vitro, or unstudied combinations only.

HOW TO USE THIS BOOK · CONTINUED

THREE PRODUCT CATEGORIES, ALWAYS KEPT APART

1. **Approved** for the stated use in at least one jurisdiction — named with the regulator, the date and the label dose.
2. **Off-label** use of an approved product — regimens appear only where an international guideline gives them, and are attributed.
3. **Unapproved or investigational** products — doses appear only as study parameters, never as clinical recommendations.

UNITS

GH concentrations are given in µg/L (1 µg/L = 1 ng/mL). IGF-1 is reported as an age- and sex-specific standard deviation score (SDS) or as a multiple of the upper limit of normal (× ULN), as the source states. Negative differences use a true minus sign.

SCOPE AND A DISCLAIMER

Growth hormone is an approved therapy with defined indications in children and adults, yet it is widely promoted for anti-aging and performance — uses that are not authorized and, in the United States, not lawful to distribute. Growth hormone secretagogues range from approved diagnostic and niche agents to unapproved research chemicals. This book states where the evidence is strong, where it is weak, and which uses are off-label or unapproved. Evidence grades reflect the evidence for the specific indication discussed, not biological plausibility.

This is educational content for licensed clinicians and a reference for clinical reasoning. It is not medical advice for any individual, does not establish a clinician–patient relationship, and does not replace specialist input or formal guidelines. Approvals, controlled-drug status and compounding rules change quickly and differ by country; statements here were verified through 15 November 2026. Verify current national sources, and confirm every citation against the primary literature, before acting.

BEFORE YOU START

Treatment starts with a proven deficiency or a labeled indication — not with a low IGF-1 alone, a symptom list, or age.

Growth hormone at a glance

The monograph's core facts on one page.

FIELD	SUMMARY
What GH is	Anterior-pituitary peptide hormone acting directly and through IGF-1. Therapeutic products are recombinant somatropin (daily) or long-acting derivatives (weekly).
Diagnosis (children)	Integrates height velocity, bone age, IGF-1/IGFBP-3, pituitary MRI and stimulation testing (PES 2016); no single test is diagnostic.
Diagnosis (adults)	Test only with a reason (pituitary disease, surgery, irradiation, TBI/SAH, childhood onset); never for somatopause. Testing may be omitted when organic hypothalamic-pituitary disease is accompanied by ≥3 other pituitary deficits and low age-adjusted IGF-1 (< −2.0 SDS), or with proven genetic/ congenital GHD. ITT peak ≤5 µg/L; glucagon ≤3 µg/L (BMI <25, or 25–30 with high pretest probability) or ≤1 µg/L (BMI >30, or 25–30 with low pretest probability). Macimorelin (<2.8 µg/L) is constrained by supply: US sales were discontinued on 23 May 2023, UK entries are flagged discontinued, and EU marketing authorization for Ghryvelin was withdrawn on 16 October 2026 (Chapter 6). Normal IGF-1 does not exclude GHD.
Diagnosis (GH excess)	IGF-1 first: above 1.3 × the upper limit of normal confirms with typical features. If equivocal, 75-g OGTT (2024 consensus: BMI-based nadirs of 0.4 µg/L if BMI <25 and 0.2 µg/L if BMI ≥25, assay-dependent; older cut-off 1 µg/L), then pituitary MRI. Chapter 8.
Products (daily)	Somatropin with a current US label: Genotropin, Norditropin, Humatrope, Omnitrope (follow-on somatropin; not a US §351(k) biosimilar), Zomacton; Serostim for HIV wasting. Nutropin AQ and Saizen are no longer marketed in the US, and Lilly states it will permanently discontinue US distribution of Humatrope on 31 December 2026, after which Zomacton is the only marketed product whose US labeling carries SHOX deficiency. Doses per each product's label.
Products (weekly)	Lonapegsomatropin (Skytrofa; US children ≥1 y and adults 2025; EU children 3–18 y; no Health Canada authorization), somapacitan (Sogroya; adults and children ≥2.5 y incl. ISS/ SGA/Noonan 2026), somatrogon (Ngenla; children ≥3 y, not adults in US).

GROWTH HORMONE AT A GLANCE · CONTINUED

FIELD	SUMMARY
Starting doses (adults)	AACE 2019: 0.3–0.4 mg/day if <30 y or on oral estrogen; 0.2–0.3 mg/day 30–60 y; 0.1–0.2 mg/day >60 y, obese or diabetic. Titrate every 1–2 months to IGF-1.
Monitoring	Adults: IGF-1 every 1–2 months in titration, then 6–12 monthly; glucose/HbA1c, lipids, free T4, cortisol axis, QoL. Children: height velocity every 3–6 months, IGF-1, thyroid, glucose, spine and hips.
Key contraindications	Active malignancy; acute critical illness; Prader-Willi syndrome in patients with severe obesity, a history of upper airway obstruction or sleep apnea, or severe respiratory impairment (evaluate for upper airway obstruction and sleep apnea before starting); active proliferative or severe non-proliferative retinopathy; closed epiphyses (for growth).
Secretagogues	Approved only for narrow uses: macimorelin (adult GHD diagnosis; US/UK discontinued, EU Ghryvelin withdrawn Oct 2026), tesamorelin (US, HIV lipodystrophy), anamorelin (Japan, cancer cachexia), GHRP-2 (Japan, diagnosis only). Ibutamoren, ipamorelin, other GHRPs, CJC-1295: no FDA, EMA or Health Canada authorization identified (verified through November 2026).
Legal status (US)	Prescription, not CSA-controlled, but knowing distribution (or possession with intent to distribute) for any use other than HHS-authorized, physician-ordered treatment of a disease or recognized medical condition is a felony under 21 U.S.C. § 333(e); anti-aging, bodybuilding and athletic uses are not authorized uses. The statute also covers analogues of somatropin. FDA: HGH is a biological product, not eligible for 503A/503B compounding exemptions.
Sport	GH, analogues, GHRH analogues, secretagogues and GHRPs: WADA S2, prohibited at all times; TUE required for legitimate GHD.

Sources: PES 2016; Endocrine Society 2011 & 2016; AACE 2019; Macrilen PI and macimorelin supply/regulatory status (Aeterna Zentaris release 5 Apr 2023; NHS dm+d; EC Decision C(2026) 7447 withdrawing Ghryvelin, 16 Oct 2026); Humatrope discontinuation notice (Eli Lilly); Genotropin, Skytrofa, Sogroya (v8, 27 Feb 2026) and Ngenla PIs; Egrifta WR PI; Wakabayashi 2021; FDA Category 2 list (22 Apr 2026); 21 U.S.C. § 333(e); DEA HGH fact sheet; WADA 2026 List. Full citations in chapter reference lists. Status verified 15 November 2026.

F P T I P L S R L F D N A M L

PART 01

Foundations

What growth hormone is, how the GH–IGF-1 axis works, how it changes across life, and how it is measured.

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