ZOMACTON®
(somatropin) for Injection
5mg and 10mg

ZoGo Support Program Enrollment Form

Please fax to 1-844-402-1027 or e-mail to
zomacton_support@occamhealth.com
Phone: 1-844-944-ZOGO (9646)
www.zomacton.com

STATEMENT OF MEDICAL NECESSITY

Patient Information

Pediatric ☐ **Adult** ☐

Patient Name (First and Last)_____ Date of Birth _____

Address_____ City_____ State_____ ZIP_____

Home Phone ( ) - Work Phone ( ) - Parent/Guardian Name_____

Cell Phone ( ) - Gender ☐ M ☐ F Primary Language_____

Current Height_____cm_____% Current Weight_____kg_____% Allergies: ☐None ☐Other_____

Insurance Information or Attach Legible Copy of Front and Back of Insurance Card

Primary Insurance_____ Patient ID # _____ Insurance Company Phone ( ) -

Pharmacy Insurance_____ Pharmacy ID #_____ Pharmacy Benefit Manager Phone ( ) -

☐ No insurance ☐ Cash Pay ☐ Please submit to patients insurance

Common ICD-10 Codes

☐ GH deficiency (includes hypopituitarism & panhypopit) (E23.0)*

☐ Postprocedural hypopituitarism (E89.3)*

☐ Hypopituitarism iatrogenic NEC (E23.1)*

☐ Idiopathic Short Stature (ISS) (R62.52)

Small for gestational age (SGA)

☐ Small for dates (P05._____) plus growth failure)

☐ Turner syndrome (Q96._____).

☐ Short stature due to endocrine disorder (SHOX) (E34.3)

☐ Fear of injections or infusions (F40.231)

☐ Other _____

Medical Assessment

Bone Age _____Y _____M

Bone X-Ray Date _____/_____/_____

Standard Deviation Height _____cm

Standard Deviation Weight _____

Growth Velocity _____cm/yr _____%

Predicted Height _____cm

Adult Only

LH _____

TSH _____

FSH _____

ACTH_____

Growth Hormone Stimulation Test Date: / /		Previous Growth Hormone Therapy: ☐ Y ☐ N
Agent 1:	Peak: ng/mL	If yes, start date _____/_____/_____ and product: _____
Agent 2:	Peak: ng/mL	IGF-1: Result:
		Other Test: Result:

Prescription Options for ZOMACTON® (choose A, B, or C, plus any additional accessories needed)

☐ **A. ZOMA-Jet 10 (needle-free)**
To be used with Needle Free Zomacton 10 mg
(NDC 55566-1902-1)

☐ **B. ZOMACTON 10mg**
(NDC 55566-1901-1)
- ☐ B-D 30 UNIT
- ☐ B-D 50 UNIT
- ☐ B-D 100 UNIT
- ☐ Other

☐ **C. ZOMACTON 5mg**
- ☐ B-D 30 UNIT
- ☐ B-D 50 UNIT
- ☐ B-D 100 UNIT
- ☐ Other

- ☐ 3cc syringe, 23g 5/8" needle
- ☐ Other

(Mix with _____mL of diluent)

Additional Accessories
- ☐ Inject Ease Device
- ☐ ZOMA-Jet 5
- ☐ Sharps Container
- ☐ Alcohol Swabs
- ☐ Travel Bag

Dose to Be Given

Dose_____mg/day_____days/wk Days Supply: ☐ 30 ☐ 90 Refills_____

Special Instructions (check all applicable boxes)

☐ One-on-One Nurse-to-Patient Training Requested

Other_____

Preferred Pharmacy_____

Has prior authority been obtained for any GH ☐ Yes ☐ No

Personal ID#_____

if yes, Date _____/_____/_____ + PPA#_____

Physician Certification

By my signature, I authorize Occam Health Services, which operates the ZoGo Patient Support Program, and its agents (collectively the "Hub") to use the information provided on this form for the purposes of verifying patient insurance coverage and benefits for ZOMACTON®, referring the patient to the ZOMACTON® Patient Assistance Program in the event the patient does not have insurance, arranging home-based training, providing educational materials, and performing business operations activities in support of these functions. I certify that I have patient consent to release this information for these purposes and that I have a signed copy on file of this patient's authorization (in a form that complies with all applicable state and federal laws) that allows me and the patient's health insurers to use and disclose the patient's health information, including his or her medical and insurance coverage information and records, to the Hub, the ZOMACTON® Patient Assistance Program, and their respective agents for the purposes described above. I understand and agree that I remain responsible for complying with all applicable federal and state laws regarding patient privacy. The authorization form signed by the patient that I have on file informs the patient that: (a) the information disclosed may include the patient's health status; (b) the patient's information may be subject to re-disclosure by the recipients and no longer protected by state or federal privacy laws; and (c) I will not condition the patient's treatment, payment, enrollment in a health plan, or eligibility for benefits on the patient providing the requested authorization. I am aware that the patient has the right to revoke the authorization at any time by calling the Hub at 1-844-944-9646 and that such revocation would end the patient's eligibility to participate in the ZoGo Patient Support Program, and that if the patient revokes the authorization, the revocation will prohibit disclosures after the date the written revocation is received, but will not affect previous disclosures made in reliance on the patient's authorization. The patient's signature will be maintained and available for audit purposes as required by all applicable state and federal privacy laws. To the best of my knowledge, all information contained in this form is correct and complete and consistent with applicable privacy laws and regulations, and I understand that the Hub is relying on this representation.

Signature _____ Date_____

Print Name_____ National Provider ID (NPI)_____ DEA #_____

Address_____ City_____ State_____ ZIP _____

Office Contact_____ Phone ( ) - Fax ( ) - Tax ID: _____

†This form cannot be processed without physician's signature.

*Post Procedural Hypopituitarism is only for GHD.

IF YOU RECEIVED THIS IN ERROR, PLEASE FAX ALL PAGES TO 1-844-402-1027 OR E-MAIL TO ZOMACTON_SUPPORT@OCCAMHEALTH.COM

ZoGo Support Program

Please see Indications for ZOMACTON® and Important Safety Information on the back.

FERRING PHARMACEUTICALS

INDICATIONS

ZOMACTON is a recombinant human growth hormone (GH) indicated for the treatment of pediatric patients with:

- growth failure due to inadequate secretion of endogenous GH
- short stature associated with Turner syndrome
- idiopathic short stature (ISS)
- short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency
- short stature born small for gestational age (SGA) with no catch-up growth by 2 to 4 years

ZOMACTON is also indicated for the replacement of endogenous GH in adults with GH deficiency

IMPORTANT SAFETY INFORMATION

Contraindications

ZOMACTON is contraindicated in patients with:

- Acute critical illness
- Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to the risk of death.
- Active malignancy.
- Hypersensitivity to ZOMACTON, its excipients, or diluents.
- Active proliferative or severe non-proliferative diabetic retinopathy.
- Pediatric patients with closed epiphyses.

Warnings and Precautions

- **Increased Risk of Neoplasm:** Second neoplasms have occurred in childhood cancer survivors. Monitor patients with preexisting tumors for progression or recurrence.
- **Glucose Intolerance and Diabetes Mellitus:** ZOMACTON may decrease insulin sensitivity, particularly at higher doses. Monitor glucose levels periodically, especially in patients with existing diabetes mellitus or at risk for development.
- **Intracranial Hypertension (IH):** Has been reported usually within 8 weeks of initiation. Perform fundoscopic examinations prior to initiation and periodically thereafter. If papilledema occurs, stop treatment.
- **Hypersensitivity:** Serious hypersensitivity reactions may occur, seek prompt medical attention.
- **Fluid Retention:** May occur in adults and may be dose dependent.
- **Hypoadrenalism:** Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism.
- **Hypothyroidism:** Monitor thyroid function periodically as hypothyroidism may occur or worsen after initiation of somatropin.
- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** May occur; evaluate patients with onset of a limp or hip/knee pain.
- **Progression of Preexisting Scoliosis in Pediatric Patients:** Monitor patients with scoliosis for progression.
- **Pancreatitis:** Has been reported; consider pancreatitis in patients with abdominal pain, especially pediatric patients.
- **Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preservative:** Serious and fatal adverse reactions can occur in neonates and infants treated with benzyl alcohol-preserved drugs, including the diluent for ZOMACTON 5 mg. If administering ZOMACTON 5 mg to infants, reconstitute with 0.9% sodium chloride injection.

Adverse Reactions

Common adverse reactions reported include: upper respiratory infection, fever, pharyngitis, headache, otitis media, edema, arthralgia, paresthesia, myalgia, carpal tunnel syndrome, peripheral edema, flu syndrome, hypothyroidism, hyperglycemia, and impaired glucose tolerance.

Drug Interactions

- **Glucocorticoids:** Patients treated with glucocorticoids may require an increased dose.
- **Pharmacologic Glucocorticoid Therapy and Supraphysysiologic Glucocorticoid Treatment:** Adjust dosing in pediatric patients to avoid hypoadrenalism or an inhibitory effect on growth.
- **Cytochrome P450-Metabolized Drugs:** Monitor carefully if used with ZOMACTON as clearance may be altered.
- **Oral Estrogen:** Larger doses of ZOMACTON may be required.
- **Insulin and/or Other Hypoglycemic Agents:** Dose adjustment may be required.

Use in Specific Populations

- **Pregnancy and Lactation:** If ZOMACTON 5 mg is needed, reconstitute with 0.9% sodium chloride injection or use the ZOMACTON 10 mg benzyl alcohol-free formulation.

Please see accompanying Full Prescribing Information for ZOMACTON®.

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