ZOMACTON™
[somatropin (rDNA origin)] for Injection
5mg and 10mg

ZoGo Support Program Enrollment Form

Previous Growth Hormone Therapy: ☐ Y ☐ N If yes, start date ____/____/____ and product:

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

PATIENT

Patient Name:	DOB: / /	Gender: ☐ M ☐ F
Patient Address:	City:	ST: ZIP:
Parent/Guardian Name:	Home Phone #:	Work/Cell Phone #:
E-mail Address:	Primary Language:	
OK to contact parent/guardian by phone ☐ or email ☐	Cash Pay ☐	Please submit to patient's insurance ☐

INSURANCE

Please attach front and back of patient's insurance card, prescription benefits card, and/or Medicaid card. Has prior authorization been obtained? ☐ Y ☐ N

Primary Insurance:		Insurance Phone #:
Subscriber Name:		Secondary Insurance:
ID #:	Group #:	Medicaid ID #:

DIAGNOSIS

☐ Isolated Growth Hormone Deficiency (ICD-10 E23.0) ☐ Other:_____

MEDICAL ASSESSMENT

Required: Fax or e-mail all supporting documentation such as bone age reports, stimulation test agents and lab results, growth charts, and progress notes to assist in the prior authorization process.

Current Height _____cm _____%	Current Weight _____kg _____%	Growth Velocity _____cm/yr _____%
Bone Age _____Y _____M	Bone X-Ray Date ____/____/____	Allergies ☐ Y_____ ☐ N
Birth Mother's Height _____cm	Birth Father's Height _____cm	Predicted Height _____cm

Growth Hormone Stimulation Test Date: / /		Other Lab Tests:	
Agent 1:	Peak: ng/mL	IGF-1:	Result:
Agent 2:	Peak: ng/mL	Test:	Result:

PRESCRIPTION

ZOMACTON™ 5 mg with:
☐ Syringe ☐ ZOMA-Jet™ 5
☐ Syringe and Inject-Ease®

ZOMACTON™ 10 mg with:
☐ Syringe
☐ Syringe and Inject-Ease®

Preferred injection syringe with ultra fine short needle *(B-D required for Inject-Ease®)*:

☐ B-D **30** unit ☐ B-D **50** unit ☐ B-D **100** unit
☐ Other:

Preferred diluent syringe for reconstitution
☐ 3cc syringe with 23g 5/8" needle
☐ Other:

☐ Sharps container
☐ Alcohol swabs
☐ Interim product for qualified patients

Preferred specialty pharmacy:

DOSAGE

Vial/Syringe and Inject-Ease®

Dose: _____ mg/injection _____ days per week

Dilute: vial with _____mL/diluent* ☐ 30-day ☐ 90-day ☐ Refill: X _____

Sig:_____

*Diluent dispensed with ZOMACTON™ 5 mg has a volume of 5 mL, 10 mg has a volume of 1 mL

ZOMA-Jet™ 5

☐ Vial Adapter 5 mg Needle-Free Head: A ☐ or B ☐

Dose: _____ mg/injection (must be in increments of 0.05 mg) _____ days per week

Dilute: 5-mg vial with **1 mL/diluent** *ZOMACTON™ sig when using ZOMA-Jet™ 5 (max dose 2.5 mg)*

☐ 30-day ☐ 90-day ☐ Refill: X _____ ☐ Patient needle phobic (F40.231)

INJECTION TRAINING

☐ In-home injection training by ZoGo Support Nurse.

PHYSICIAN

Name:			Office Contact:	
Address:			City:	ST: ZIP:
NPI #:	DEA #:	Tax ID #:	Phone #:	Fax #:

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.

Physician Authorization	X _____ Date / /

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 Indication for ZOMACTON™ and Important Safety Information on the back.

FERRING PHARMACEUTICALS

Indication

ZOMACTON™ [somatropin (rDNA origin)] for injection is indicated for the treatment of children who have growth failure due to an inadequate secretion of normal endogenous growth hormone.

Important Safety Information

Contraindications

- **Hypersensitivity:** Somatropin is contraindicated in patients with a known sensitivity to somatropin or the supplied diluent. Localized reactions are the most common hypersensitivity reactions. Patients with a known sensitivity to either benzyl alcohol or metacresol should not receive somatropin reconstituted with the supplied diluent.
- **Closed Epiphyses:** Somatropin should not be used for growth promotion in pediatric patients with closed epiphyses.
- **Diabetic Retinopathy:** Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy.
- **Active Malignancy:** Somatropin is contraindicated in patients with any evidence of active malignancy. Growth hormone deficiency may be an early sign of a pituitary tumor or other intracranial tumor; the presence of such a tumor should be excluded before initiation of somatropin treatment.
- **Acute Critical Illness:** Somatropin should not be used to treat patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure. In adult patients, a significant increase in mortality has been reported in such cases.
- **Prader-Willi Syndrome in Children:** Somatropin is contraindicated in patients with Prader-Willi syndrome who are severely obese or have severe respiratory impairment. Somatropin is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

Warnings and Precautions

- **Acute Critical Illness:** Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic doses of somatropin.
- **Prader-Willi Syndrome in Children:** There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. Patients with Prader-Willi syndrome should be evaluated for signs of upper airway obstruction and sleep apnea before initiation of treatment with somatropin.
- **Pancreatitis:** Cases of pancreatitis have been reported rarely in children and adults receiving somatropin, with some evidence supporting greater risk in children. Pancreatitis should be considered in any somatropin-treated patient, especially a child, who develops abdominal pain. Girls who have Turner syndrome may be at greater risk than other somatropin-treated children.
- **Benzyl Alcohol:** Benzyl alcohol, a component used to reconstitute the ZOMACTON™ 5-mg vial, has been associated with serious adverse events and death, particularly in pediatric patients. The "gasping syndrome," has been associated with benzyl alcohol dosages >99 mg/kg/day in neonates and low-birth weight neonates. Additional symptoms may include gradual neurological deterioration, seizures, intracranial hemorrhage, hematologic abnormalities, skin breakdown, hepatic and renal failure, hypotension, bradycardia, and cardiovascular collapse. Practitioners administering this and other medications containing benzyl alcohol should consider the combined daily metabolic load of benzyl alcohol from all sources.
- **Neoplasms:** An increased risk of a second neoplasm has been reported for childhood cancer survivors treated with somatropin for GH deficiency that developed following radiation to the brain/head. Intracranial tumors, in particular meningiomas, were the most common of these. The relationship between somatropin replacement therapy and CNS tumor recurrence in adults is unknown. Monitor for progression or recurrence in patients receiving somatropin therapy who have a history of GH deficiency secondary to an intracranial neoplasm. Thoroughly consider the risks and benefits of starting somatropin in children at increased risk for developing malignancies due to certain rare genetic causes. These patients should be carefully monitored for development of neoplasms. Any pre-existing nevi should be monitored carefully for increased growth or malignant transformation.
- **Glucose Intolerance and Diabetes Mellitus:** Previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked during somatropin treatment. New-onset type 2 diabetes mellitus has been reported. As a result, blood glucose concentrations should be monitored periodically in all patients taking somatropin, especially in those with risk factors for diabetes mellitus. Patients with pre-existing type 1 or type 2 diabetes mellitus or impaired glucose tolerance should be monitored closely during somatropin treatment.
- **Hypopituitarism:** In patients with hypopituitarism, standard hormone replacement therapy should be monitored closely when somatropin therapy is administered.
- **Hypothyroidism:** Patients treated with somatropin should have periodic thyroid function tests, and thyroid hormone replacement therapy should be initiated or appropriately adjusted in cases of unmasked or worsening hypothyroidism.
- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** Slipped capital femoral epiphysis may occur more frequently in patients with endocrine disorders and in patients undergoing rapid growth. Any pediatric patient with the onset of a limp or complaints of hip or knee pain during somatropin therapy should be carefully evaluated.
- **Intracranial Hypertension:** Intracranial hypertension with papilledema, visual changes, headache, nausea, and/or vomiting have been reported in a small number of patients treated with somatropin. Funduscopic examination is recommended at the initiation of and periodically during therapy. If papilledema is observed by funduscopy during treatment with somatropin, treatment should be stopped and the patient's condition should be reassessed before treatment is resumed.
- **Progression of Scoliosis in Pediatric Patients:** Progression of scoliosis can occur in patients who experience rapid growth. Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis.
- **Epiphyseal Maturation:** Bone age should be monitored periodically during somatropin administration, especially in patients who are pubertal and/or receiving concomitant thyroid hormone replacement therapy. Under these circumstances, epiphyseal maturation may progress rapidly.
- **Local and Systemic Reactions:** Injection site should be rotated to avoid tissue atrophy. Patients should be informed that local or systemic allergic reactions may occur and that prompt medical attention should be sought in such cases.
- **Laboratory Tests:** Serum levels of inorganic phosphorus, alkaline phosphatase, parathyroid hormone and IGF-I may increase after somatropin therapy.
- **Potential Drug Interactions:** Somatropin inhibits 11β-hydroxysteroid dehydrogenase type 1 (11βHSD-1) in adipose/hepatic tissue and may significantly impact the metabolism of cortisol and cortisone. As a consequence, in patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked, requiring glucocorticoid replacement therapy. Careful monitoring is advisable when growth hormone is administered in combination with insulin and/or other hypoglycemic agents, other drugs metabolized by CYP450 liver enzymes (e.g., hydrocortisone or other corticosteroids, sex steroids, anticonvulsants, cyclosporine), or other hormone replacement therapy.
- **Pregnancy/Nursing Mothers:** Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk.

Adverse Reactions

The following adverse reactions have been observed during appropriate use of somatropin: headaches (children and adults), gynecomastia (children), and pancreatitis (children and adults). In studies of growth hormone-deficient children, injection-site reactions (e.g., pain, bruise) occurred in 8 of the 164 treated patients. Leukemia and new-onset type 2 diabetes mellitus have been reported.

Please see accompanying Full Prescribing Information for ZOMACTON™.

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[somatropin (rDNA origin)] for Injection
5mg and 10mg

ZOMA-Jet™ 5
For use with ZOMACTON™ 5 mg only.