ZOMACTON®

(somatropin) for Injection
5mg and 10mg

ZOMACTON® 5mg & 10mg

DOSING UPDATE

Please see Indication and Important Safety Information throughout and accompanying Full Prescribing Information for ZOMACTON®.

Indication

ZOMACTON® (somatropin) for Injection is a recombinant human growth hormone (GH) indicated for:

- **Pediatric Patients:** Treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous GH
- **Adult Patients:** Replacement of endogenous GH in adults with GH deficiency

PEDIATRIC DOSAGE[1]

The recommended weekly doses in milligrams (mg) per kilogram (kg) of body weight are:

- 0.18 to 0.30 mg/kg/week
- Divide the calculated weekly doses into equal doses given either 3, 6, or 7 days per week

ADULT DOSAGE[1]

Either of the following two dosing regimens may be used:

- Non-weight-based dosing: Initiate with a dose of approximately 0.2 mg/day (range, 0.15 mg/day-0.3 mg/day) and increase the dose every 1-2 months in increments of approximately 0.1 mg/day-0.2 mg/day, according to individual patient requirements
- Weight-based dosing (Not recommended for obese patients): Initiate at 0.006 mg/kg daily and increase the dose according to individual patient requirements to a maximum of 0.0125 mg/kg daily

ZOMACTON® should be administered subcutaneously in pediatric and adult patients.[1]

Important Safety Information

CONTRAINDICATIONS

ZOMACTON® is contraindicated in patients with:

- Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or with acute respiratory failure due to the risk of increased mortality.
- 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:** An increased risk of a second neoplasm has been reported in childhood cancer survivors. Monitor patients with preexisting tumors for progression or recurrence or have a history of GH deficiency secondary to an intracranial neoplasm.
- **Glucose Intolerance and Diabetes Mellitus:** ZOMACTON® may decrease insulin sensitivity, particularly at higher doses. New-onset type 2 diabetes mellitus has been reported. Monitor glucose levels periodically in all patients, especially in patients with existing diabetes mellitus or at risk for development. Doses of antidiabetic agents may require adjustment.
- **Intracranial Hypertension:** Intracranial hypertension with papilledema, visual changes, headache, nausea, and/or vomiting have been reported in a small number of patients. Fundoscopic examination should be performed before initiating treatment and periodically. Stop treatment if papilledema occurs.
- **Hypersensitivity:** Serious hypersensitivity reactions including anaphylactic reactions and angioedema may occur when using somatropin products. Seek prompt medical attention if an allergic reaction occurs.
- **Fluid Retention:** Fluid retention may occur 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.
- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** Slipped capital femoral epiphysis may occur. Evaluate patients with onset of a limp or hip/knee pain.

Please see additional Important Safety Information on next page and accompanying Full Prescribing Information for ZOMACTON®.

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Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Progression of Preexisting Scoliosis in Pediatric Patients:** Progression of scoliosis can occur. Patients with a history of scoliosis should be monitored.
- **Pancreatitis:** Pancreatitis has been reported and should be considered in patients with abdominal pain, especially pediatric patients.
- **Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preservative:** Serious and fatal reactions can occur in neonates and infants treated with benzyl alcohol-preserved drugs, including the diluent for ZOMACTON® 5 mg vial. Reconstitute with normal saline, if administering ZOMACTON® 5 mg to infants.
- **Lipoatrophy:** Injection sites should be rotated to avoid tissue atrophy.

ADVERSE REACTIONS

Most common adverse reactions (10% or greater incidence) in adult and pediatric patients include: upper respiratory infection, fever, pharyngitis, headache, otitis media, edema, arthralgia, paresthesia, myalgia, pain, rhinitis, peripheral edema, back pain, flu syndrome, and AST increased.

DRUG INTERACTIONS

- **Glucocorticoids:** Patients treated with glucocorticoids may require an increased dose.
- **Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment:** Should be carefully adjusted 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 normal saline, or use the ZOMACTON® 10 mg benzyl alcohol-free formulation.

Please see accompanying Full Prescribing Information for ZOMACTON®.

Reference: 1. ZOMACTON [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.

FERRING PHARMACEUTICALS

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