

## Zomacton® (somatropin) – New indications

- On July 19, 2018, [Ferring announced](#) the FDA approval of [Zomacton \(somatropin\)](#), for the treatment of pediatric patients with short stature associated with Turner syndrome; idiopathic short stature, height standard deviation score  $\leq -2.25$  and associated with growth rates unlikely to permit attainment of adult height in the normal range; short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency; and short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age.
- Zomacton is also approved for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH); and for the replacement of endogenous GH in adults with GH deficiency.
- The approval of Zomacton’s new indications were based on one long-term, open-label trial in patients with Turner syndrome; two placebo-controlled trials and 1 dose-response study in patients with idiopathic short stature; a 2-year, open-label study in patients with SHOX deficiency, and a 2-year, open-label trial in patients with SGA.
  - Refer to the Zomacton drug label for further information about the clinical studies.
- The recommended subcutaneous (SC) dose of Zomacton should be individualized for each patient based on the growth response.

Population	Indication	Dosage Regimen
Pediatric	GH deficiency	0.18 mg/kg/week – 0.3 mg/kg/week
	Turner syndrome	Up to 0.375 mg/kg/week
	Idiopathic short stature	Up to 0.37 mg/kg/week
	SHOX deficiency	0.35 mg/kg/week
	SGA	Up to 0.47 mg/kg/week
Adults	GH deficiency (non-weight based approach)	Approximately 0.2 mg/day and increase every 1 to 2 months by ~0.1 mg/day to 0.2 mg/day according to individual patient requirements
	GH deficiency (weight based approach)	0.006 mg/kg daily and increase according to individual patient requirements up to a maximum of 0.0125 mg/kg/day

- In pediatric patients, divide the calculated weekly dose of Zomacton into equal doses and administer SC either 3, 6, or 7 days per week.
  - In adult patients, administer the prescribed dose of Zomacton daily.
  - Therapy with Zomacton should be supervised by a physician who is experienced in the diagnosis and management of patients with the conditions for which Zomacton is indicated.
  - Refer to the Zomacton drug label for additional dosing information.
- In September, Zomacton will be available to use with the ZOMA-Jet 10 Needle-Free Delivery System.