GENRYZON® Summary of Product Information

GENERIC NAME: Somatrogon injection **PRESENTATION**: Somatrogon 24 mg/1.2 ml solution for injection in pre-filled pen and Somatrogon 60 mg/1.2 ml solution for injection in pre-filled pen. **INDICATION(s)**: Somatrogon is indicated for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone **DOSAGE AND ADMINISTRATION:** The recommended dose is 0.66 mg/kg body weight administered once weekly by subcutaneous injection. Each pre-filled pen is capable of setting and delivering the dose prescribed by the physician. When doses higher than 30 mg are needed (i.e., bodyweight > 45 kg), two injections have to be administered. For patients switching from daily growth hormone medicinal products, the weekly therapy with somatrogon may be initiated at a dose of 0.66 mg/kg/week on the day following their last daily injection. Somatrogon dose may be adjusted as necessary, based on growth velocity, adverse reactions, body weight and serum insulin-like growth factor 1 (IGF-1) concentrations. Somatrogon is administered by subcutaneous injection. Somatrogon is to be injected in the abdomen, thighs, buttocks, or upper arms. The site of injection should be rotated at each administration. Treatment should be discontinued when there is evidence of closure of the epiphyseal growth plates. Treatment should also be discontinued in patients having achieved final height or near final height. The safety and efficacy of somatrogon in patients over the age of 65 years have not been established. Somatrogon has not been studied in patients with renal impairment and hepatic impairment. The safety and efficacy of somatrogon in neonates, infants and children less than 3 years of age have not yet been established. **CONTRAINDICATIONS:** Hypersensitivity to somatrogon or to any of the excipients. Somatrogon must not be used when there is any evidence of activity of a tumour based on experience with daily growth hormone medicinal products. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting growth hormone (GH) therapy. Treatment should be discontinued if there is evidence of tumour growth. Somatrogon must not be used for growth promotion in children with closed epiphyses. Patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions must not be treated with somatrogon. **WARNING AND PRECAUTIONS**: **Hypersensitivity**-Serious systemic hypersensitivity reactions (e.g. anaphylaxis, angioedema) have been reported with daily growth hormone medicinal products. **Hypoadrenalism**- Based on published data patients receiving daily growth hormone therapy who have or are at risk for pituitary hormone deficiency(s) may be at risk for reduced serum cortisol levels and/or unmasking of central (secondary) hypoadrenalism. **Thyroid function**- Growth hormone increases the extrathyroidal conversion of T4 to T3 and may unmask incipient hypothyroidism. **Prader-Willi syndrome**- Somatrogon has not been studied in patients with Prader-Willi syndrome. **Glucose metabolism**- Treatment with growth hormone medicinal products may reduce insulin sensitivity and induce hyperglycaemia. **Neoplasm**- In patients with previous malignant disease, special attention should be given to signs and symptoms of relapse. **Benign intracranial hypertension**- Intracranial hypertension (IH) with papilledema, ataxia, visual changes, headache, nausea and/or vomiting has been reported in a small number of patients treated with growth hormone medicinal products. **Acute critical illness**- The benefits of continued somatrogon treatment in this situation should be weighed against the potential risks involved **Pancreatitis** -Although rare in patients treated with growth hormone medicinal products, pancreatitis should be considered in somatrogon-treated patients **Scoliosis**- Because somatrogon increases growth rate, signs of development or progression of scoliosis should be monitored during treatment. **Epiphyseal disorders**- Any paediatric patient with the onset of a limp or complaints of hip or knee pain during treatment should be carefully evaluated. **Oral oestrogen therapy**- If a female patient taking somatrogon begins or discontinues oral oestrogen containing therapy, IGF-1 value should be monitored to determine if the dose of growth hormone should be adjusted to maintain the serum IGF-1 levels within the normal range. **DRUG INTERACTIONS**: No interactions studies in paediatrics have been performed. **Glucocorticoids-** Concomitant treatment with glucocorticoids may inhibit the growth-promoting effects of somatrogon. **Insulin and hypoglycaemic medicinal products**- In patients with diabetes mellitus requiring medicinal product therapy, the dose of insulin and/or oral/injectable hypoglycaemic medicinal products may require adjustment when somatrogon therapy is initiated. **Thyroid medicinal products** - Treatment with daily growth hormone may unmask previously undiagnosed or subclinical central hypothyroidism. **Oral oestrogen therapy**- In female patients on oral oestrogen-containing therapy, a higher dose of somatrogon may be required. Drug-drug interaction studies have not been performed with somatrogon. Somatrogon has been shown to induce CYP3A4 mRNA expression in vitro. The clinical significance of this is unknown. **OVERDOSE**: Single doses of somatrogon higher than 0.66 mg/kg/week have not been studied. Based on experience with daily growth hormone medicinal products, short-term overdose could lead initially to hypoglycaemia and subsequently to hyperglycaemia. Long-term overdose could result in signs and symptoms of gigantism and/or acromegaly consistent with the effects of growth hormone excess. Treatment of overdose with somatrogon should consist of general supportive measures. **ADVERSE REACTION**: **Very common (≥ 1/10)**- Injection site reactions (injection site pain, erythema, pruritus, swelling, induration, bruising, haemorrhage, warmth, hypertrophy, inflammation, deformation, urticaria), Pyrexia **Common (≥ 1/100 to < 1/10)**- Anaemia, Eosinophilia, Hypothyroidism, Conjunctivitis Allergic, Arthralgia, Pain in extremity. **PHARMACEUTICAL PRECAUTIONS**: Store in a refrigerator (2 °C to 8 °C). Do not freeze. Keep somatrogon in the outer carton to protect from light. **PHARMACOKINETICS / PHARMACODYNAMICS:** Following subcutaneous injection, serum concentrations increased slowly, peaking 6 to 18 hours after dosing. There is no accumulation of somatrogon after once weekly administration. In paediatric patients with GHD, the population PK estimated steady-state peak concentrations following 0.66 mg/kg/week was 636 ng/mL. In paediatric patients with GHD, the population PK estimated apparent central volume of distribution was 0.728 L/kg and apparent peripheral volume of distribution was 0.165 L/kg. The metabolic fate of somatrogon is believed to be classical protein catabolism, with subsequent reclamation of the amino acids and return to the systemic circulation. In paediatric patients with GHD, the population PK estimated apparent clearance was 0.0317 L/h/kg. With a population PK estimated effective half-life of 28.2 hours, somatrogon will be present in the circulation for about 6 days after the last dose.

REFERENCE: Adapted from Local Product document GENRYZON LPDGEN092022

Full prescription information available on request. For the use only of registered medical practitioner, or a hospital or a laboratory