NOVARTIS

SANDOSTATIN® LAR®

(octreotide acetate)

10 mg, 20 mg, 30 mg powder and solvent for suspension for injection

Basic Succinct Statement

Acromegaly & PNET indication - IPL; NET indication- EU

Code: BSS RD 30 APR 20; APPR 01 NOV 20
This material is only meant for Healthcare Professionals

Version 3.1

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Important note: Before prescribing, consult full prescribing information.

Presentations:

Kit with vial adapter and safety needle: Octreotide acetate. Vials containing 10 mg, 20 mg or 30 mg octreotide free peptide supplied as powder (microspheres) for suspension for injection together with a prefilled syringe (solvent for parenteral use), containing: sodium carboxymethylcellulose (14 mg), mannitol (12 mg), poloxamer 188 (4 mg), water for injection qs ad 2 mL; vial adapter, one safety needle.

Indications: ♦Treatment of patients with Acromegaly: in whom surgery or radiotherapy is inappropriate or ineffective; or in the interim period until radiotherapy becomes fully effective. ♦Treatment of patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumors: carcinoid tumors with features of the carcinoid syndrome, VIPomas, glucagonomas, gastrinomas/Zollinger-Ellison syndrome, insulinomas, for pre-operative control of hypoglycemia and for maintenance therapy , GRFomas. ♦Treatment of patients with advanced neuroendocrine tumors of the midgut or of unknown primary origin where non-midgut sites of origin have been excluded.

Dosage regimen and administration: 10 to 40 mg every 4 weeks, administered as a deep intragluteal injection.

Contraindications: Known hypersensitivity to octreotide or to any of the excipients.

Warnings and Precautions: ♦Dose adjustments of drugs such as antidiabetics, beta-blockers, calcium channel blockers, or agents to control fluid and electrolyte balance, may be necessary; ♦Caution in patients with insulinomas. ♦Caution in patients with diabetes mellitus. ♦Thyroid function should be monitored in patients receiving prolonged treatment with octreotide. ♦Periodic examination of gallbladder. ♦Monitoring of vitamin B_{12} levels in patients who have a history of vitamin B_{12} deprivation.

Adverse drug reactions: ♦**Very common (≥1/10)** adverse drug reactions are: diarrhea, abdominal pain, nausea, constipation, flatulence, headache, cholelithiasis, hyperglycemia, and injection-site reaction. ♦**Common (≥1/100, <1/10)** adverse drug reactions are: dyspepsia, vomiting, abdominal bloating, steatorrhea, loose stools, discoloration of faeces, dizziness, asthenia, hypothyroidism, thyroid disorder (e.g. decreased thyroid stimulating hormone [TSH], decreased Total T4, and decreased Free T4), cholecystitis, biliary sludge, hyperbilirubinemia, hypoglycemia, impairment of glucose tolerance, anorexia, elevated transaminase levels, pruritus, rash, alopecia, dyspnea, and bradycardia. ♦**Uncommon (≥1/1000, <1/100)** adverse drug reactions are: dehydration, and tachycardia. ♦**Post-marketing** the following adverse reactions have been reported: anaphylaxis, isolated cases of anaphylactic shock, allergy/hypersensitivity reactions, urticaria, acute pancreatitis, acute hepatitis without cholestasis, cholestatic hepatitis, cholestasis, jaundice, cholestatic jaundice, arrhythmia, thrombocytopenia, increased alkaline phosphatase levels, and increased gamma glutamyl transferase levels.