NOVARTIS

SANDOSTATIN®

(octreotide acetate)

Ampoules 0.05 mg/1 mL, 0.1 mg/1 mL, solution for injection (s.c.) or concentrate for solution for infusion (i.v. infusion)

Basic Succinct Statement

Code: PI RD 11 SEP 17; APPR 9 APR 18
This material is only meant for Healthcare Professionals

Version 2.0

SANDOSTATIN®

Important note: Before prescribing, consult full prescribing information.

Presentation: Octreotide acetate. Ampoules containing 0.05 and 0.1 mg octreotide (as free peptide) per 1 mL.

Indications: ♦Acromegaly: in patients inadequately controlled by surgery, or radiotherapy, or unsuitable for such procedures; in the interim period until radiotherapy becomes fully effective. ♦Relief of symptoms associated with functional gastro-entero-pancreatic endocrine tumours: carcinoid tumours with features of the carcinoid syndrome, VIPomas, glucagonomas, gastrinomas/Zollinger-Ellison syndrome, insulinomas, GRFomas.

♦Prevention of complications following pancreatic surgery. Emergency management of bleeding gastro-oesophageal varices in patients with cirrhosis.

Dosage and administration: Acromegaly and gastro-entero-pancreatic endocrine tumours*:* Initially 0.05 to 0.1 mg s.c. once or twice daily; increase gradually up to 0.1 to 0.2 mg t.i.d. if necessary. Complications following pancreatic surgery*:* 0.1 mg t.i.d. by s.c. injection for 7 consecutive days, starting on the day of operation, at least 1 hour before laparotomy. Bleeding gastro-oesophageal varices*:* 25 micrograms/hour for 5 days by continuous i.v. infusion. Sandostatin can be used in dilution with physiological saline.

The solution should reach room temperature before s.c. 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, diabetes mellitus; ♦Thyroid function should be monitored in patients receiving prolonged treatment with octreotide. Beware of sudden escape from symptomatic control by Sandostatin with rapid recurrence of severe symptoms. Periodic examination of gallbladder; ♦Monitoring of vitamin B_{12} levels in patients who have a history of vitamin B_{12} deprivation; blood glucose levels mandatory in patients treated for bleeding gastro-oesophageal varices; ♦Caution in patients with pregnancy, patients should be advised to use adequate contraception if necessary. Patients should not breast feed-during Sandostatin treatment.

Interactions: ♦Impaired intestinal absorption of ciclosporin, cimetidine; increased bioavailability of bromocriptine. ♦Caution with concomitant use of drugs mainly metabolized by CYP3A4 and which have a low therapeutic index. ♦Dose adjustments of drugs such as antidiabetics, beta-blockers, calcium channel blockers, or agents to control fluid and electrolyte balance, may be necessary.

Adverse drug reactions:

♦**Very common (≥ 1/10)**) adverse drug reactions are diarrhoea, abdominal pain, nausea, constipation, flatulence, headache, cholelithiasis, hyperglycaemia, and injection-site reaction.

♦**Common (≥ 1/100, < 1/10)**) adverse drug reactions are dyspepsia, vomiting, abdominal bloating, steatorrhoea, loose stools, discolouration of faeces, dizziness, asthenia, hypothyroidism, thyroid disorder(e.g., decreased thyroid stimulating hormone [TSH], decreased Total T4, and decreased Free T4), cholecystitis, biliary sludge, hyperbilirubinaemia, hypoglycaemia, impairment of glucose tolerance, anorexia, elevated transaminase levels, pruritus, rash, alopecia, dyspnoea 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, thrombocytopenia, acute pancreatitis, acute hepatitis without cholestasis, cholestatic hepatitis, cholestasis, jaundice, cholestatic jaundice, arrhythmia, increased alkaline phosphatase levels, and increased gamma glutamyl transferase levels.

(Occurrence of gastrointestinal side effects may be reduced by avoiding meals around the time of Sandostatin administration).