

Segment 1, Industrial Road, Dayi county, Chengdu, Sichuan, P. R. China, 611330 Tel: 86-28-88208155, Fax: 86-28-88203632 WEB: www.kjpep.com

About Author

Chengdu Kaijie Biopharm Co, Ltd. (KJBP) is one of leading peptide manufacturers in Asia. With its highest capacity of production in China and the outstanding quality of peptide products, Kaijie holds a unique position.

Octreotide

1. US Trade Names: Sandostatin ,Sandostatin LAR Depot

2. How Supplied

2.1. Generic

Injection Solution: 50 MCG/ML, 100 MCG/ML, 200 MCG/ML, 500 MCG/ML, 1000 MCG/ML

2.2. Sandostatin

Injection Solution: 100 MCG/ML, 200 MCG/ML, 500 MCG/ML, 1000 MCG/ML

2.3. Sandostatin LAR Depot

Intramuscular Powder for Suspension: 10 MG, 20 MG, 30 MG



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3. Adult Dosing

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate: initial, 50 mcg SUBQ/IV 3 times daily (octreotide acetate injection)

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate: maintenance, 100-500 mcg SUBQ/IV 3 times daily (octreotide acetate injection)

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate: initial (as conversion from octreotide acetate injection), 20 mg IM intragluteally at 4-week intervals for 3 months (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate: after initial 3 months, continue 20 mg IM intragluteally every 4 weeks if GH is less than or equal to 2.5 ng/mL, IGF-I is normal, and clinical symptoms have improved (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesulate: after initial 3 months, increase to 30 mg IM intragluteally every 4 weeks if GH is greater than 2.5 ng/mL, IGF-I is elevated, and/or clinical symptoms uncontrolled (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate: after initial 3 months, decrease to 10 mg IM intragluteally every 4 weeks if GH is less than or equal to 1 ng/mL, IGF-I is normal, and clinical symptoms are controlled (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Acromegaly, Inadequate response to or ineligible for surgery, radiation, or bromocriptine mesylate: increase dose to 40 mg IM intragluteally every 4 weeks in patients whose GH, IGF-1, and symptoms are not adequately controlled at 30 mg (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Carcinoid syndrome, Metastatic; symptomatic treatment: initial, 100-600 mcg/day SUBQ/IV in 2-4 divided doses for 2 weeks (octreotide acetate injection)

Carcinoid syndrome, Metastatic; symptomatic treatment: maintenance, 450 mcg/day SUBQ/IV (range 50-1500 mcg/day; experience with doses above 750 mcg/day is limited) (octreotide acetate injection)



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Carcinoid syndrome, Metastatic; symptomatic treatment: initial, 20 mg IM intragluteally at 4-week intervals for 2 months (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot)); continue SUBQ octreotide acetate injections for at least 2 weeks during the switch to octreotide acetate injectable suspension

Carcinoid syndrome, Metastatic; symptomatic treatment: after 2 months of initial therapy, increase dose to 30 mg IM intragluteally every 4 weeks if symptoms not adequately controlled (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Carcinoid syndrome, Metastatic; symptomatic treatment: after 2 months of initial therapy, decrease dose to 10 mg IM intragluteally in patients who achieve good symptom control; increase dose to 20 mg IM every 4 weeks if symptoms recur (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Insulinoma: Optimal dosing and timing not yet defined

Non-infective diarrhea: Optimal dosing and timing not yet defined

Vasoactive intestinal peptide-secreting tumor, Associated diarrhea: initial, 200-300 mcg SUBQ/IV in 2-4 divided doses for 2 weeks (range 150-750 mcg) (octreotide acetate injection)

Vasoactive intestinal peptide-secreting tumor, Associated diarrhea: maintenance, adjust to achieve therapeutic response (usually not more than 450 mcg/day SUBQ/IV is required) (octreotide acetate injection)

Vasoactive intestinal peptide-secreting tumor, Associated diarrhea: initial, 20 mg IM intragluteally at 4-week intervals for 2 months (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot)) continue SUBQ octreotide acetate injections for at least 2 weeks during the switch to octreotide acetate injectable suspension

Vasoactive intestinal peptide-secreting tumor, Associated diarrhea: after 2 months of initial therapy, increase dose to 30 mg IM intragluteally every 4 weeks if symptoms not adequately controlled (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))

Vasoactive intestinal peptide-secreting tumor, Associated diarrhea: after 2 months of initial therapy, decrease dose to 10 mg IM intragluteally in patients who achieve good symptom control; increase dose to 20 mg IM every 4 weeks if symptoms recur (octreotide acetate injectable suspension (Sandostatin LAR(R) Depot))



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4. Pediatric Dosing

Safety and efficacy in children not established

5. Dose Adjustments

Renal impairment (adults), octreotide acetate injection: dosage adjustments may be necessary in patients with severe renal failure requiring dialysis since the half-life of the drug can be increased

Renal impairment requiring dialysis (adults), octreotide acetate suspension (Sandostatin LAR(R) Depot): the starting dose should be 10 mg every 4 weeks

Renal impairment, mild, moderate, or severe, not requiring dialysis (adults), octreotide acetate suspension (Sandostatin LAR(R) Depot): no dose adjustment is required for the starting dose

Hepatic impairment (adults; cirrhotic patients), octreotide acetate suspension (Sandostatin LAR(R) Depot): the starting dose should be 10 mg every 4 weeks .

6. Mechanism of Action

Octreotide acetate, a cyclic octapeptide agent, inhibits growth hormone, glucagon, and insulin more effectively than the natural hormone, somatostatin. Its suppression of luteinizing hormone's (LH) response to gonadotrophin releasing hormone (GnRH) and inhibition of the release of serotonin, gastrin, vasoactive intestinal peptide (VIP), secretin, motilin, and pancreatic polypeptide are similar to somatostatin's actions. The drug also reduces growth hormone and/or IGF-I (somatomedin C) in acromegaly, inhibits gallbladder contractions, reduces bile secretion and suppresses the secretion of thyroid stimulating hormone (TSH).

7. Adverse Effects

Dermatologic: Injection site pain

Endocrine metabolic: Hyperglycemia (1.5% to 16%), Hypoglycemia (1.5% to 3%),

Hypothyroidism

Gastrointestinal: Abdominal discomfort, Cholelithiasis (22% to 33%), Constipation, Diarrhea,

Flatulence, Nausea, Pancreatitis

Hepatic: Disorder of biliary tract **Neurologic:** Dizziness, Headache