

OCTREOTIDE (Systemic)

Category

Antidiarrheal (gastrointestinal tumor; acquired immunodeficiency syndrome [AIDS]); growth hormone suppressant (acromegaly); antihemorrhagic (bleeding gastroesophageal varices); antihypotensive (carcinoid crisis); antihypoglycemic (pancreatic tumor).

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Tumors, gastrointestinal (treatment adjunct) % Octreotide is indicated for palliative management of gastrointestinal endocrine tumors, such as:

Carcinoid tumors % To suppress or inhibit the associated severe diarrhea and facial flushing episodes. 1, 2, 5

Vasoactive intestinal polypeptide-secreting tumors (VIPomas) % For the treatment of the profuse watery diarrhea associated with VIPomas. 1, 2

Acromegaly (treatment) % Octreotide is indicated to suppress secretion of growth hormone from pituitary tumors and decrease blood concentrations of insulin-like growth factor-I (IGF-I; somatomedin C) in patients with acromegaly who have not optimally responded to or cannot be treated with surgical resection or pituitary irradiation or have been unable to tolerate bromocriptine. Octreotide may be used as adjunctive therapy with irradiation to help relieve symptoms of acromegaly and possibly slow the rate of tumor growth. 1, 2, 4, 7, 10, 13

[Pancreatic surgery, complications of (prophylaxis)] % Octreotide is indicated to reduce the incidence and severity of the postoperative complications of high-risk pancreatic surgery. These complications may include abscess formation and subsequent sepsis, acute pancreatitis, pancreatic fistula, and peripancreatic fluid collection. 7

[Varices, gastroesophageal, bleeding (treatment)] % Octreotide, with an appropriate adjunctive therapeutic intervention such as sclerotherapy, is indicated to control bleeding and early rebleeding and to reduce transfusion requirements in patients with bleeding gastroesophageal varices associated with cirrhosis. Octreotide has been shown to improve the 5-day survival rate in these patients. 7

[Hypotension (treatment)] * % Octreotide is indicated to reverse life-threatening hypotension due to carcinoid crisis during induction of anesthesia. 3

[Tumors, pancreatic (treatment adjunct)] * % Octreotide is indicated for use as palliative treatment of the symptoms resulting from hyperinsulinemia from severe refractory metastatic insulinoma. 20, 21, 22, 25

[Diarrhea, acquired immunodeficiency syndrome (AIDS)-associated (treatment)] *¾Octreotide is indicated in AIDS patients with severe secretory diarrhea who have failed to respond to antimicrobial or antimotility agents. 9, 16, 17, 18, 19, 25

* Not included in Canadian product labeling.

Other actions/effects:

Octreotide suppresses secretion of glucagon, insulin, and thyroid stimulating hormone, 1, 2, 7 and suppresses the luteinizing hormone response to gonadotropin-releasing hormone. 1, 2, 7 Octreotide also inhibits gallbladder contractions 1, 2, 9, 10, 13, 14 and decreases bile secretion. 1, 2

Precautions to Consider

Carcinogenicity

Lifetime carcinogenicity studies in male and female mice receiving octreotide at subcutaneous doses of 0.4 mg, 1.2 mg, and 2 mg per kg of body weight (mg/kg) per day demonstrated an increase in the incidence of duodenal mucosal hyperplasia in the females. 7

Studies in male and female Wistar rats administered octreotide subcutaneously for up to 116 weeks demonstrated an increased incidence of subcutaneous sarcomata in males receiving 0.24 and 1.25 mg/kg per day. Additionally, in the females, there were dose-related increases in ovarian sections without corpora lutea and uterine glandular and luminal dilatation; endometriosis was seen in all treated groups, particularly the 1.25-mg/kg-per-day group. There was a marginal but statistically significant increase in the relative proportion of lymphocytes in males receiving 0.8 and 1.25 mg/kg per day (8 to 10% increase) and in females receiving 1.25 mg/kg per day (16% increase). 7 All groups of treated males and females receiving 0.8 and 1.25 mg/kg per day experienced dose-related weight loss. 7

Mutagenicity

No evidence of mutagenicity was demonstrated in vitro with the Ames test or in vivo with the micronucleus test or unscheduled DNA synthesis (UDS) assay. 7

Pregnancy/Reproduction

Fertility¾Studies in rats at doses of up to 1000 mcg per kg of body weight (seven times the human exposure based on body surface area) a day have not shown that octreotide causes impaired fertility. 1, 2, 7

Pregnancy¾ Adequate and well-controlled studies in humans have not been done. 1, 2, 7

Studies in rats and rabbits at doses of up to 30 times the maximum human dose have not shown that octreotide causes adverse effects in the fetus. 7

FDA Pregnancy Category B. 1, 2

Breast-feeding

It is not known whether octreotide is distributed into breast milk. 1, 2, 7

Pediatrics

Appropriate studies with immediate-release octreotide have not been performed in the pediatric population. However, doses of 1 to 10 mcg per kg of body weight, given to children as young as 1 month old, were well tolerated. One case in which an infant (a case of nesidioblastosis) suffered a seizure while undergoing octreotide therapy was thought to be unrelated to octreotide administration. 1, 7

Safety and efficacy of long-acting octreotide in pediatric patients have not been established. 2

Geriatrics

Studies performed to date in patients as old as 83 years of age have not demonstrated geriatrics-specific problems that would limit the usefulness of this medication in the elderly. However, the half-life may be significantly increased (by up to 46%) and the clearance significantly decreased (by as much as 26%), which may require adjustment of dosage in elderly patients receiving octreotide. 1, 2

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate) ¼ not necessarily inclusive (>> = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

>> Antidiabetic agents, sulfonylurea 7 or

>> Diazoxide, oral 7 or

>> Glucagon or

>> Growth hormone or

>> Insulin 1, 2, 7

(use of these medications during octreotide therapy may result in hypoglycemia or hyperglycemia; patient monitoring and dosage adjustment of these medications may be necessary 1, 2, 7)

Beta-adrenergic blocking agents 1, 2

(because of the bradycardic effect of octreotide, dosage adjustment may be required 1, 2)

Cyclosporine 1, 2, 7

(a single case of transplant rejection [renal/whole pancreas] in a patient who was receiving octreotide and who was immunosuppressed with cyclosporine has been reported; the use of octreotide to reduce exocrine secretion and close a fistula in this patient resulted in a decrease in the blood concentrations of cyclosporine, thus possibly contributing to the rejection episode 7, 9)

Laboratory value alterations

The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)^{3/4}not necessarily inclusive (>> = major clinical significance):

With diagnostic test results

Schilling test 1, 2

(abnormal results have been seen 1, 2)

With physiology/laboratory test values

Alanine aminotransferase (ALT [SGPT]) 7 and

Alkaline phosphatase 7 and

Aspartate aminotransferase (AST [SGOT]) 7 and

Gamma-glutamyltransferase (GGT), serum 7

(values may be increased if hyperbilirubinemia develops 7)

Electrocardiogram 1, 2

(changes such as QT prolongation, axis shifts, early repolarization, low voltage, R/S transition, R-wave progression, and nonspecific ST-T wave changes have been seen in patients with acromegaly 1, 2)

Thyroid hormones

(serum concentration of thyroxine [T 4] may be decreased; hypothyroidism occurred in one clinical trial patient [with a carcinoid tumor] after 19 months of receiving 1.5 mg of octreotide daily 7)

Vitamin B 12, serum 1, 2

(concentrations may be decreased 1, 2)

Zinc, serum 2

(concentrations may increase excessively in patients receiving total parenteral nutrition [TPN] when fluid loss is corrected 2)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¼ not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problems exist

>> Diabetes mellitus

(therapy used to control glycemc states may need to be adjusted 1, 2, 7)

>> Gallbladder disease or gallstones, or history of

(increased risk of cholelithiasis possibly due to alteration of fat absorption and decrease in gallbladder motility caused by octreotide 1, 7, 13, 14, 24)

Renal function impairment, severe

(half-life of octreotide may be increased; dosage adjustment may be necessary 1, 2, 7)

Sensitivity to octreotide 1, 2, 7

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; >> = major clinical significance):

Carotene, serum concentrations and

Fecal fat, quantitative 7

(octreotide therapy may alter absorption of dietary fats; periodic 72-hour fecal fat and serum carotene determinations are recommended to assess possible aggravation of fat malabsorption 7)

Glucose

(measurement of blood concentrations is recommended at the beginning of octreotide therapy and at each change of dosage if clinical signs of increase or decrease occur 1, 7, 12, 13, 14)

>> Growth hormone 1, 2, 7

(recommended at 1- to 4-hour intervals for 8 to 12 hours following a dose of immediate-release octreotide and at 6-month intervals thereafter to assess response in patients with acromegaly; 1, 2, 7 after transfer to the long-acting dosage form, monitoring is recommended at 3-month intervals 2)

>> 5-hydroxyindoleacetic acid (5-HIAA), quantitative, urine 1, 2, 7 and

Serotonin 1, 2 and

Substance P, plasma 1, 2, 7

(periodic determinations are recommended during therapy in patients with carcinoid tumors to assess patient response 1, 2)

Insulin-like growth factor-I (IGF-I; somatomedin C) 1, 2, 7

(an alternative to measurement of growth hormone; may be measured one time 2 weeks after immediate-release octreotide initiation or change of dosage and at 6-month intervals thereafter to assess response in patients with acromegaly; 1, 2, 7 after transfer to the long-acting dosage form, monitoring is recommended at 3-month intervals 2)

Thyroid function determinations 1, 2

(baseline and periodic thyroid function tests using total and free serum thyroxine [T₄] are recommended during chronic therapy 1, 2, 7)

>> Ultrasonograms

(therapy with octreotide, as with the natural hormone somatostatin, may be associated with cholelithiasis, presumably due to an alteration of fat absorption and possibly to decreased motility of the gallbladder; baseline and periodic ultrasonograms may be required to assess the presence of gallstones 11, 13)

Vasoactive intestinal polypeptide (VIP) 1, 2, 7

(periodic determinations are recommended in patients with VIP-secreting tumors [VIPomas] to assess patient response 1, 2)

Vitamin B₁₂, serum 1, 2

(periodic determinations are recommended during chronic therapy 1, 2)

Zinc, serum 2

(periodic determinations are recommended in patients receiving TPN 2)

Side/Adverse Effects

Note: Isolated reports of hepatic dysfunctions associated with octreotide administration include acute hepatitis without cholestasis, slow development of hyperbilirubinemia, and gallstone formation. 7 The risk of gallstone formation increases with long-term therapy, which usually is required in the treatment of acromegaly. 7, 11, 13

Development of antibodies has been seen in up to 25% of patients treated with octreotide. In most of these cases, therapeutic response to octreotide has not been affected. However, in two patients with acromegaly, the duration of growth hormone suppression following an injection of immediate-release octreotide was doubled as compared with that in patients without antibodies. 2

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate) not necessarily inclusive:

Those indicating need for medical attention

Incidence more frequent

Arrhythmias (irregular heartbeat) incidence 9% in patients with acromegaly, 1, 2 3% in patients with carcinoid tumors 2; bradycardia (slow heartbeat) incidence 25% in patients with acromegaly, 1 19% in patients with carcinoid tumors 2

Incidence less frequent or rare

Hyperglycemia (blurred vision; drowsiness; dry mouth; flushed, dry skin; fruit-like breath odor; increased urination [frequency and volume]; ketones in urine; loss of appetite; stomachache, nausea, or vomiting; tiredness; troubled breathing [rapid and deep]; unconsciousness; unusual thirst) 1, 2, 7; hypoglycemia (anxiety; behavior change similar to drunkenness; blurred vision; cold sweats; coma; confusion; cool, pale skin; difficulty in concentrating; drowsiness; excessive hunger; fast heartbeat; headache; nausea; nervousness; nightmares; restless sleep; seizures; shakiness; slurred speech; unusual tiredness or weakness) 1, 2, 7; pancreatitis, acute (abdominal pain or distension; nausea; vomiting) 1, 7

Note: Octreotide therapy is occasionally associated with mild transient hypoglycemia or hyperglycemia due to an alteration in the balance between the counterregulatory hormones, insulin, glucagon, and growth hormone. 1, 2, 9, 12, 13

Acute pancreatitis generally is seen within the first hours or days of octreotide administration and resolves when therapy is discontinued. 7

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent

Gastrointestinal symptoms (abdominal or stomach pain or discomfort; constipation; diarrhea; flatulence; nausea and vomiting) 1, 2, 7; pain, stinging, tingling, or burning sensation at injection site, with redness and swelling 1, 2, 7

Note: Gastrointestinal symptoms usually are self-limiting and usually are resolved after 2 to 3 weeks of therapy. 13, 25

Incidence less frequent or rare

Alopecia 1, 7; dizziness or lightheadedness 1, 2, 7; edema (swelling of feet or lower legs); fatigue 1, 2; fever 2, 7; headache 1, 2; redness or flushing of face 1, 7; unusual weakness 1, 7

Overdose

For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing).

Clinical effects of overdose

The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:

Abdominal cramps 7; decrease in heart rate 7; diarrhea 7; dizziness 2; empty feeling in stomach 7; flushing of face 2, 7; nausea 2, 7

Treatment of overdose

Supportive care¾Recommended treatment consists of temporary withdrawal of octreotide and symptomatic treatment of the clinical effects. 7

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Octreotide (Systemic) .

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Sensitivity to octreotide

Other medications, especially glucagon, growth hormone, insulin, oral diazoxide, or sulfonylurea antidiabetic agents

Other medical problems, especially diabetes mellitus or gallbladder disease or gallstones

Proper use of this medication

>> Taking medication only as directed by physician

>> Reading directions in starter kit before using

>> Carefully selecting and rotating injection sites

Allowing medication to reach room temperature if pain, stinging, tingling, or burning sensation occurs upon injection

>> Safe handling and disposal of needles and syringes; not reusing needles and syringes 7

>> Proper dosing

Missed dose:

Long-acting dosage form¾Contacting physician

Immediate-release dosage form¾Using as soon as possible unless almost time for next dose, then going back to regular dosing schedule; 7 not doubling doses

>> Proper storage

Precautions while using this medication

>> Importance of close monitoring by physician

Side/adverse effects

Signs of potential side effects, especially arrhythmias, bradycardia, hyperglycemia, hypoglycemia, and acute pancreatitis

General Dosing Information

Preferred sites for subcutaneous administration of octreotide injection (immediate-release dosage form) are the hip, thigh, and abdomen. 7

Octreotide suspension (long-acting dosage form) is recommended for intragluteal administration only. Injection into the deltoid muscle causes significant discomfort at the site. 2 Intravenous or subcutaneous administration is not recommended. 2

Multiple injections at the same injection site within short periods of time are not recommended. 1, 2, 7, 15 This is to avoid irritating the area. 2, 7

Local reactions at the injection site may be minimized by allowing the medication to reach room temperature before injection and by administering slowly. 7

Periodic exacerbation of symptoms may occur despite good overall control. During these times, if the patient is receiving octreotide injection, the dosage should be adjusted. 7 If the patient is receiving octreotide suspension, octreotide injection, at the previous dosage, should be administered concurrently with octreotide suspension until symptoms are again controlled. Administration of octreotide injection may then be discontinued. 2

For gastrointestinal tumors

When initiating therapy with octreotide suspension, octreotide injection, at the current dosage, should be administered concurrently for at least 2 weeks (up to 4 weeks may be required in some patients) to allow octreotide suspension to reach therapeutic concentrations. Failure to do so may result in exacerbation of symptoms. 2

For acromegaly

If after 3 months there is no significant decrease in growth hormone concentration and no appreciable improvement in clinical symptoms, octreotide therapy should be discontinued. 7

Octreotide therapy should be withheld for approximately 8 weeks each year from patients who have received irradiation, to assess disease activity. During this time, if growth hormone or insulin-like growth factor-I (IGF-I) concentration increases or if clinical signs and symptoms recur, octreotide therapy should be reinstated. 1

Diet/Nutrition

To avoid the occurrence of gastrointestinal side effects, injections of octreotide should be scheduled between meals and at bedtime. 7

Parenteral Dosage Forms

Note: Bracketed uses in the Dosage Forms section refer to categories of use and/or indications that are not included in U.S. product labeling.

OCTREOTIDE ACETATE FOR INJECTABLE SUSPENSION

Usual adult and adolescent dose

Gastrointestinal tumors%

Patients not currently receiving octreotide%To ascertain responsiveness to octreotide, it is recommended that therapy be initiated and maintained for at least two weeks with the immediate-release dosage form (see Octreotide Acetate Injection). 2

Patients currently receiving octreotide injection: Intragluteal, 20 mg every four weeks for two months. Dosage may then be increased to 30 mg every four weeks or decreased to 10 mg every four weeks, based on patient response. 2

Note: Administration of octreotide injection at the current dosage should be maintained for at least two weeks to allow octreotide suspension to reach therapeutic concentrations. 2

Acromegaly%

Patients not currently receiving octreotide%

To ascertain responsiveness to octreotide, it is recommended that therapy be initiated and maintained for at least two weeks with the immediate-release dosage form (see Octreotide Acetate Injection). 2

Patients currently receiving octreotide injection%

Intragluteal, 20 mg every four weeks for three months. Dosage should then be titrated based on the following criteria:

If growth hormone concentrations are less than 2.5 nanograms per mL, IGF-I concentrations are normal, and clinical symptoms are controlled%Intragluteal, 20 mg every four weeks. 2

If growth hormone concentrations are greater than 2.5 nanograms per mL, IGF-I concentrations are elevated, and/or clinical symptoms are uncontrolled%Intragluteal, 30 mg every four weeks. 2

If growth hormone concentrations are less than or equal to 1 nanogram per mL, IGF-I concentrations are normal and clinical symptoms are controlled%Intragluteal, 10 mg every four weeks. 2

If growth hormone concentrations, IGF-I concentrations, and clinical symptoms are not controlled with 30 mg%Intragluteal, 40 mg every four weeks. 2

Note: Administration at dosing intervals greater than every four weeks is not recommended; efficacy at this schedule has not been determined. 2

Because of the increase in the half-life of octreotide, patients with renal failure requiring dialysis may need an adjustment in the dosage. 2

Usual adult prescribing limits

Gastrointestinal tumors¾30 mg every four weeks. 2

Acromegaly¾40 mg every four weeks. 2

Usual pediatric dose

Safety and efficacy have not been established. 2

Usual geriatric dose

See Usual adult and adolescent dose .

Note: Because of the significant increase in the half-life of octreotide and the decrease in clearance seen in geriatric patients, dosage adjustment may be required. 2

Size(s) usually available:

U.S.¾10 mg (base) per vial (Rx)[Sandostatin LAR Depot 2]

20 mg (base) per vial (Rx)[Sandostatin LAR Depot 2]

30 mg (base) per vial (Rx)[Sandostatin LAR Depot 2]

Canada¾Not commercially available.

Packaging and storage:

Store at 2 to 8 °C (36 to 46 °F), 2 unless otherwise specified by manufacturer. Protect from light. 2

Note: Octreotide for injectable suspension vial and diluent should be taken from the refrigerator 30 to 60 minutes before administration to allow them to warm to room temperature. 2

Preparation of dosage form:

The manufacturer's instructions for preparation should be followed. 2

Stability:

Octreotide suspension should be administered immediately after preparation. 2

Auxiliary labeling:

- Refrigerate.

Note: Injection sites should be rotated. 2

OCTREOTIDE ACETATE INJECTION

Usual adult and adolescent dose

Gastrointestinal tumors^¾

Subcutaneous, 50 mcg initially, administered two or three times a day, the dose being increased gradually according to patient tolerance and response. 1 The following dosages are recommended for specific tumors:

Carcinoid tumors^¾

Initial: Subcutaneous, 100 to 600 mcg per day, administered in two to four divided doses, for the first two weeks of therapy. 1, 2, 7

Maintenance: Subcutaneous, 50 to 1500 mcg per day. In clinical trials, the median maintenance dosage was 450 mcg per day. 1, 7

Vasoactive intestinal polypeptide-secreting tumors (VIPomas):

Subcutaneous, 200 to 300 mcg per day, administered in two to four divided doses, for the first two weeks of therapy. Dosage may then be increased based on patient response. 1, 7

Acromegaly^¾

Subcutaneous or intravenous, initially 50 mcg three times a day. Dosage is titrated every two weeks as needed, according to IGF-I concentrations, to a dose of 100 1, 2, 13 to 200 2 mcg three times a day; or, for rapid titration, dosage increase may be based on multiple serum growth hormone concentrations taken at one- to four-hour intervals over eight to twelve hours. 13 Doses of up to 500 mcg three times a day have been used rarely. 1, 13

Note: Octreotide injection may be administered subcutaneously (the preferred route) or intravenously. To help prevent pain at the injection site, octreotide should be given in the smallest volume needed to achieve the proper dose. In emergencies, intravenous injections may be used cautiously. 1

If an increase in dose fails to provide additional benefit, the dose should be reduced. 1

[Complications of pancreatic surgery (prophylaxis of)]^¾

Subcutaneous, 100 mcg three times a day for seven days beginning on the day of surgery at least one hour before laparotomy. 7

[Bleeding gastroesophageal varices]^¾

Intravenous infusion, 25 mcg per hour for forty-eight hours. Infusion should continue for up to five days in patients at high risk for rebleeding. 7

[Pancreatic tumors] ^{*¾}

Subcutaneous, 50 to 150 mcg initially, administered two times a day thirty minutes before meals, the dose being increased gradually according to patient tolerance and response. 20, 21

[Acquired immunodeficiency syndrome (AIDS)-associated diarrhea] ^{*¾}

Subcutaneous, 100 to 1800 mcg per day. 16, 17, 18, 19, 25

Usual adult prescribing limits

Acromegaly 1500 mcg daily. 7

Usual pediatric dose

Gastrointestinal tumors 7

Subcutaneous, 1 to 10 mcg per kg of body weight per day. 1

Usual geriatric dose

See Usual adult and adolescent dose .

Note: Because of the significant increase in the half-life of octreotide and the decrease in clearance seen in geriatric patients, dosage adjustment may be required. 1

Strength(s) usually available

U.S. 50 mcg per mL (Rx)[Sandostatin 1]

100 mcg per mL (Rx)[Sandostatin 1]

200 mcg per mL (Rx)[Sandostatin 1]

500 mcg per mL (Rx)[Sandostatin 1]

1000 mcg per mL (Rx)[Sandostatin 1]

Note: The 50 mcg per mL, 100 mcg per mL, and 500 mcg per mL strengths are packaged as single-use ampuls; the remaining strengths are packaged as multiple-dose vials. 1

Canada 50 mcg per mL (Rx)[Sandostatin 7]

100 mcg per mL (Rx)[Sandostatin 7]

200 mcg per mL (Rx)[Sandostatin 7]

500 mcg per mL (Rx)[Sandostatin 7]

Note: The 50 mcg per mL, 100 mcg per mL, and 500 mcg per mL strengths are packaged as single-use ampuls; the 200 mcg per mL strength is packaged as a multiple-dose vial. 7

Packaging and storage:

Octreotide may be stored at room temperature protected from light for up to 14 days. 1, 7, 15
However, for prolonged periods, store at 2 to 8 °C (36 to 46 °F), 7 unless otherwise specified by manufacturer. Protect from freezing. 7 Protect from light. 1, 7

Note: Solution should be allowed to warm to room temperature before administration. Do not warm artificially before injection. Single-use ampuls should be opened just prior to use and any unused portion discarded. 1, 7

Preparation of dosage form:

Octreotide is stable when diluted in 50 to 200 mL of either sterile 0.9% sodium chloride injection or 5% dextrose injection. The diluted solution can be infused intravenously over a 15- to 30-minute period or administered via a direct intravenous injection over a 3-minute period. 1, 15 In emergencies, rapid intravenous injections may be used cautiously. 1

Stability:

If protected from light, octreotide injection is stable at room temperature, preferably between 15 and 30 °C (59 and 86 °F), for 14 days. When diluted in 0.9% sodium chloride injection, octreotide injection is stable at room temperature for 24 hours. 7 Octreotide should not be used if it is discolored or if particulate matter forms in the solution. 1, 7

Incompatibilities:

Octreotide is not compatible with fat emulsions 15 or with total parenteral nutrition (TPN) solutions because decreased efficacy may result if glycosyloctreotide conjugates form. 1

Note: Subcutaneous injection sites should be rotated. 7, 15

References

1 Sandostatin package insert (Novartis%US), Rev 01/97, Rec 02/23/99.

2 Sandostatin LAR Depot package insert (Novartis%US), Rev 11/98, Rec 02/23/99.

3 Kvols LK, Martin JK, Marsh HM, et al. Rapid reversal of carcinoid crisis with a somatostatin analogue. N Engl J Med 1985; 313(19): 1229-30.

4 Ch'ng LJC, Sandler LM, Kraenzlin ME, et al. Long term treatment of acromegaly with a long acting analogue of somatostatin. BMJ 1985; 290(6464): 284-5.

5 Kvols LK, Moertel CG, O'Connell MJ, et al. Treatment of the malignant carcinoid syndrome. N Engl J Med 1986; 315(11): 663-6.

6 Lamberts SW. A guide to the clinical use of the somatostatin analogue SMS 201-995 (Sandostatin). Acta Endocrinol Suppl (Copenh) 1987; 286: 54-66.

7 Sandostatin product monograph (Novartis%Canada), Rev 03/02/98, Rec 06/17/98.

8 O'Donnell LJ, Farthing MJ. Therapeutic potential of a long-acting somatostatin analogue in gastrointestinal diseases. Gut 1989; 30(9): 1165-72.

9 Pon D, Dong BJ. Octreotide use in AIDS. Drug Information Analysis Service (DIAS). Ann Pharmacother 1990 Oct; 24: 951-2.

10 Harris AG, Prestele H, Herold K, et al. Long-term efficacy of Sandostatin (SMS 201-995, octreotide) in 178 acromegalic patients: results from the International Multicentre Acromegaly Study group. In: Lamberts SWJ, editor. Sandostatin in the treatment of acromegaly. Consensus Round Table; 1987; Amsterdam. Berlin: Springer; 1988. p. 117-25.

11 Roti E, Minelli R, Gardini E, et al. Chronic treatment with long-acting somatostatin analogue in a patient with intestinal carcinoid tumor: occurrence of cholelithiasis. J Endocrinol Invest 1990 Jan; 13: 69-72.

12 Popovic V, Nesovic M, Kendereski A, et al. Hypoglycemia in acromegalic patient treated with long acting somatostatin analogue. Horm Metab Res 1989 May; 21: 282-4.

13 Ho KY, Weissberger AJ, Marbach P, et al. Therapeutic efficacy of the somatostatin analog SMS 201-995 (octreotide) in acromegaly. Ann Intern Med 1990 Feb; 112(3): 173-81.

14 McKnight JA, McCance DR, Crothers JG, et al. Changes in glucose tolerance and development of gall stones during high dose treatment with octreotide for acromegaly. BMJ 1989 Sep; 299: 604-5.

15 Trissel LA, editor. Handbook on injectable drugs. 10th ed. Bethesda, MD: American Society of Health-System Pharmacists Inc; 1998. p. 909.

16 Katz MD, Erstad BL, Rose C. Treatment of severe cryptosporidium-related diarrhea with octreotide in patient with AIDS. DICP 1988; 22: 134-6.

17 Cook DJ, Kelton JG, Stanisz AM, et al. Somatostatin treatment for cryptosporidial diarrhea in a patient with the acquired immunodeficiency syndrome (AIDS). Ann Intern Med 1988; 108(5): 708-9.

18 Robinson EN, Fogel R. SMS 201-995, a somatostatin analogue, and diarrhea in the acquired immunodeficiency syndrome (AIDS) [letter]. Ann Intern Med 1988; 109: 680-1.

19 Fuebl HS, Zoller WG, Kochen MM, et al. Treatment of secretory diarrhea in AIDS with the somatostatin analogue SMS 201-995. Klin Wochenschr 1989; 67: 452-5.

20 Longnecker SM. Remission of symptoms of chemotherapy-refractory metastatic insulinoma using octreotide. DICP 1988; 22: 136-8.

21 Wood SM, Kraenzlin ME, Adrian TE, et al. Treatment of patients with pancreatic endocrine tumors using a new long-acting somatostatin analog: symptomatic and peptide responses. Gut 1985; 26: 438-44.

22 Ch'ng JLC, Anderson JV, Williams SJ, et al. Remission of symptoms during long-term treatment of metastatic pancreatic endocrine tumors with long-acting somatostatin analog. BMJ 1986; 292(6526): 981-2.

23 Canada JR, editor. USP dictionary of USAN and international drug names 1998. Rockville, MD: The United States Pharmacopeial Convention Inc; 1997. p. 525.

24 Manufacturer comment.

25 Panel comments, 3/91.

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