Octreotide Acetate Injection
in a prefilled syringe

Combining the octreotide you know with the innovation of a prefilled syringe, Mylan gives clinicians an option with patient care in mind.

Dose alternatives
Mylan offers octreotide in three strengths:
- Octreotide acetate injection 50 mcg/mL
- Octreotide acetate injection 100 mcg/mL
- Octreotide acetate injection 500 mcg/mL

Designed with hospitals in mind
Prefilled octreotide syringes offer hospital clinicians the ready-to-administer medicine they need.

Storage flexibility
- If protected from light, octreotide is stable for 15 days at room temperature
- For prolonged storage, keep at refrigerated temperatures 2°C to 8°C (36°F to 46°F) and protected from light.

Indications and Usage
Octreotide Acetate Injection is indicated to reduce blood levels of growth hormone (GH) and IGF-1 (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.

Octreotide Acetate Injection is indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing associated with VIP-secreting tumors.

In acromegals, improvement in the clinical signs and symptoms or reduction in tumor size were not demonstrated in clinical trials with Octreotide Acetate Injection; these trials were not designed to detect such effects. In patients with carcinoid syndrome or VIP-secreting tumors, the effect of Octreotide Acetate Injection on size, rate of growth or reduction in tumor size has not been determined.

Important Safety Information
In clinical trials, the incidence of biliary tract abnormalities was 63% (27% gallstones, 24% sludge without stones, and 12% biliary duct dilatation). The following may occur: hypoglycemia or hyperglycemia (blood glucose levels should be monitored when treatment is initiated or when the dose is altered); bradycardia, arrhythmia, conduction abnormalities and other EKG changes, particularly in acromegalic patients. Octreotide Acetate may alter absorption of dietary fats. Monitoring of vitamin B12 levels is recommended during chronic therapy. Female patients of childbearing potential should be advised to use adequate contraception during octreotide treatment since normalization of GH and IGF-1 may restore fertility. The following drugs may require dose adjustment when used with Octreotide Acetate: insulin, oral hypoglycemic agents, ß-blockers, calcium channel blockers, agents to control fluid and electrolyte balance, pain medication, and prednisone. Patients on propranolol for thyrotoxicosis or bradycardia have been treated with Octreotide Acetate without problems. Patients taking octreotide with chronic hypothyroidism or treated with prednisone have been treated with added care to monitor thyroid function and adrenal function. Safety and efficacy in the pediatric population have not been established.

Important Safety Information

In acromegalics, diarrhea, loose stools, nausea and abdominal discomfort may occur and develop in patients on chronic Octreotide Acetate therapy. In acromegalics, sinus bradycardia <50 bpm, developed in 25%, conduction abnormalities occurred in 10%, and arrhythmias in 9% were each seen in 34% to 61% of patients, although only 2.6% of patients discontinued due to these symptoms. These symptoms were seen in 5% to 10% of patients with other disorders.

Adverse reactions including intestinal obstruction and thrombocytopenia have been identified; however, it is not always possible to establish a causal relationship to drug exposure.

Adverse events following accidental overdose include arrhythmia, hypotension, cardiac arrest, brain hypoxia, pancreatitis, hepatitis steatosis, hepatomegaly, lactic acidosis, flushing, diarrhea, lethargy, weakness, and weight loss. If overdose occurs, symptomatic management is indicated.

Dosage varies for each indication. Please see full Prescribing Information for dosage and administration information.

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<th>Wholesaler Number</th>
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Important Safety Information (continued)

recommended; tachycardia, arrhythmia, conduct abnormalities and other DGI-changes, particularly in acromegalic patients. Octreotide Acetate may alter absorption of dietary fats. Monitoring of vitamin D12 levels is recommended during chronic therapy. Female patients of childbearing potential should be advised to use adequate contraception during octreotide treatment since normalization of Gf and Gf-1 may restore fertility. The following drugs may require dose adjustment when used with Octreotide Acetate: insulin, oral hypoglycemic agents, ß-blocking agents, calcium channel blockers, anti-embolism prophylaxis, bromocriptine and cyclosporine. Safety and efficacy in the pediatric population have not been demonstrated. Clinical studies did not include sufficient numbers of patients aged 65 and over to determine if response differs from younger subjects.

Gallbladder: Gallbladder abnormalities, especially stones and/or biliary sludge, frequently occur in 34% to 61% of patients, although only 2.6% of patients discontinued due to these symptoms. These symptoms were seen in 1% to 10% of patients with other disorders. Hypoglycemia and hyperglycemia occurred in 5% and 16% of acromegalic patients, respectively.

In acromegalics, biochemical hyperthyroidism alone occurred in 12% while goiter occurred in 6%. Pain on injection was reported in 7%, headache in 6% and dizziness in 5%. Paraneoplastic was also observed. Adverse reactions including mechanical obstruction and thrombocytopenia have been identified; however, it is not always possible to establish a causal relationship to drug exposure. Adverse events following accidental overdose include arrhythmia, hypotension, cardiac arrest, lethargy, weakness, and weight loss. If overdose occurs, symptomatic management is indicated. Dosage varies for each indication. Please see full Prescribing Information for dosage and administration information.

Important Safety Information (continued)

Important Safety Information

Octreotide Acetate Injection is indicated for the treatment of the profuse watery diarrhea episodes associated with VIP-secreting tumors.

In acromegalics, improvement in the clinical signs and symptoms or reduction in tumor size were each seen in 34% to 61% of patients, although only 2.6% of patients discontinued due to these symptoms.

Adverse reactions including mechanical obstruction and thrombocytopenia have been identified; however, it is not always possible to establish a causal relationship to drug exposure.

Adverse events following accidental overdose include arrhythmia, hypotension, cardiac arrest, lethargy, weakness, and weight loss. If overdose occurs, symptomatic management is indicated.

Dosage varies for each indication. Please see full Prescribing Information for dosage and administration information.

Please see enclosed full Prescribing Information.

For more information or to order products, please contact Mylan Institutional Customer Relations: 800.848.0462

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DESCRIPTION: Octreotide acetate is a cyclic decapeptide prepared as a clear sterile solution of octreotide acetate, salt in a solution of acetic acid and sodium chloride and preserved with sodium hydroxide to adjust pH, and water for injection, q.s.

CLINICAL PHARMACOLOGY: Octreotide acetate exerts pharmacologic actions similar to the natural hormone, somatostatin. It is an octapeptide that inhibits various gastrointestinal functions, including gastric acid, biliopancreatic secretions, and gallbladder contraction. Octreotide acetate inhibits growth hormone (GH) and IGF-I (somatomedin C) levels in patients with acromegaly.

Vasoactive Intestinal Peptide Tumors (VIPomas): Octreotide acetate reduces the growth of VIP-secreting tumors, reduces diarrhea associated with VIP-secreting tumors.

Octreotide acetate substantially reduces growth hormone and/or IGF-I (somatomedin C) levels in patients with acromegaly. The suggested daily dosage of octreotide acetate during the first 2 weeks of therapy ranges from 100 to 300 mcg in 2 to 4 divided doses. Subsequent daily dosage may be reduced to half the original daily dosage every 2 weeks until the desired response is achieved, or every week, or every 2 weeks, or even monthly depending on the clinical judgment. titration. Alternatively, a single measurement of IGF-I (somatomedin C) level every 2 weeks can be used to guide titration.

Hematologic: The incidence of anemia was less than 5% in patients who received octreotide acetate for injectable suspension. No effect on platelets was observed.

Cardiac: In acromegalics, sinus bradycardia (< 50 bpm) developed in 25%; conduction abnormalities occurred in 10% and arrhythmias were generally minor.

Gastrointestinal: Post-Marketing Experience: In acromegalics, abdominal pain (including severe epigastric pain, abdominal tenderness and guarding) were each seen in less than 10% of patients.

Hypoglycemia and hyperglycemia occurred in 3% and 16% of acromegalic patients, respectively, but only in 12% and 13% of non-acromegalic patients, respectively. Levels of glucose were not increased in pancreas cancer patients who received octreotide acetate. Patients with VIP-secreting tumors may be at risk for glucagonomas and glucose intolerance.

Hepatitis, jaundice, increase in liver enzymes, GI bleeding, hemorrhoids, appendicitis, gastric/peptic ulcer, gallbladder disease, arthritis, joint effusion, muscle pain, Raynaud's phenomenon.

None of the above side effects for patients who will require higher doses. IGF-I (somatomedin C) levels every 2 weeks can be used to guide titration. Alternative, a single measurement of IGF-I (somatomedin C) level every 2 weeks can be used to guide titration. Alterna-

Urogenital: galactorrhea, hypoadrenalism, diabetes insipidus, gynecomastia, amenorrhea, polymenorrhea, oligomenorrhea, vaginitis.

Upper respiratory: rhinitis, pharyngitis, sinusitis, paronychia, purpura

In controlled clinical trials the incidence of gallstone or biliary sludge formation was markedly increased (see WARNINGS).

ALIMENTARY: In acromegaly, abdominal pain (including severe epigastric pain, abdominal tenderness and guarding) were each seen in less than 10% of patients.

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dialysis (ClCR < 10 mL/min) t 1/2 was 3.1 hours and total body clearance was 7.6 L/hr. In patients with severe renal failure requiring octreotide acetate therapy and died.

Gallbladder Abnormalities: In patients with Vasoactive Intestinal Peptide Tumors (VIPomas):

The incidence of stones or sludge in patients who received octreotide acetate injection to reduce blood levels of growth hormone and IGF-I (somatomedin C) offers potential benefit before the 50% to 60% of patients. Since the effects of pituitary irradiation may not become maximal for several years, adjunctive therapy with octreotide acetate may be resumed.

Energy metabolism: Indications and usage: Acromegaly: Dose adjustments in drugs such as beta-blockers that have bradycardia effects may be necessary. In one acromegalic patient with mean serum insulin levels, the effects of octreotide acetate were variable and maintained.

Other Adverse Events: Gastrointestinal: In post-marketing data, a limited number of exposed pregnancies have been reported in patients with acromegaly. Most women who conceived while receiving octreotide acetate remained on therapy through the pregnancy and the drug was continued after delivery.

The hypoglycemia or hyperglycemia which occurs during octreotide acetate therapy is usually mild, but may result in overt diabetes mellitus.

It is not known whether octreotide is excreted into human milk. Because many drugs are excreted in human milk, caution should be exercised when octreotide acetate is administered to a nursing woman.

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