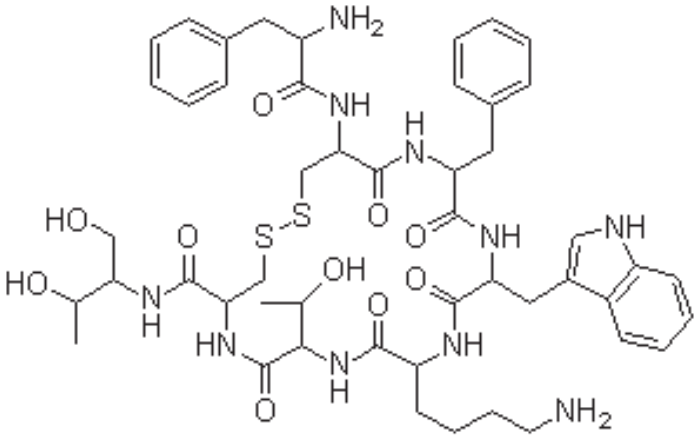
Taj Pharmaceuticals Ltd.

Octreotide Acetate

CAS No. : 79517-01-4

Systematic (IUPAC) name

(4R,7S,10S,13R,16S,19R)-10-(4-aminobutyl)-19-[[(2R)-2-amino-3-phenyl-propanoyl]amino]-16-benzyl-N-[(2R,3R)-1,3-dihydroxybutan-2-yl]-7-(1-hydroxyethyl)-13-(1H-indol-3-ylmethyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentazacycloicosane-4-carboxamide



D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Threoninol

Identifiers

Molecular Formula C49H66N10O10S2
Molecular Weight 1019.24
CAS Registry Number 79517-01-4
ATC code H01CB02
PubChem 54373
DrugBank BTD00088

Chemical data

Formula C49H66N10O10S2
Mol. mass 1019.24 g/mol

DOSAGE

Withdraw octreotide yearly for approximately 4 wk from patients who received irradiation to assess disease activity. If GH or IGF-1 levels increase and signs and symptoms recur, therapy may be resumed.

Adults

IV / Subcutaneous 50 mcg 3 times daily. Although 100 mcg 3 times daily is the most commonly effective dosage, some patients require up to 500 mcg 3 times daily.

Patients not currently receiving octreotide

Before administering the octreotide long-acting depot formulation , patients not currently receiving octreotide should begin therapy with octreotide immediate-release formulation given subcutaneously in an initial dosage of 50 mcg 3 times daily. Most patients require 100 to 200 mcg 3 times daily, but some patients require 500 mcg 3 times daily. After maintaining patients on subcutaneous octreotide for at least 2 wk to determine tolerance, patients who are considered responders can be switched to administration of the intragluteal long-acting depot formulation in a dose of 20 mg given IM intragluteally at 4-wk intervals for 3 months; dosage may be adjusted as follows:
GH 2.5 ng/mL or less, IGF-1 normal and clinical symptoms controlled

Maintain octreotide depot dosage at 20 mg every 4 wk.
GH greater than 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled
Increase the octreotide depot dosage to 30 mg every 4 wk.
GH 1 ng/mL or less, IGF-1 normal and clinical symptoms controlled
Reduce the octreotide depot dosage to 10 mg every 4 wk.
GH, IGF-1, or symptoms are not adequately controlled at a dose of 30 mg
The dosage may be increased to 40 mg every 4 wk. Higher doses are not recommended.
Dosage adjustments after 2 months

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If symptoms are adequately controlled, consider a dose reduction to 10 mg for a trial period. If symptoms recur, dosage should be increased to 20 mg every 4 wk. If symptoms are not adequately controlled, increase the octreotide long-acting depot dose to 30 mg every 4 wk. Patients who achieve good control on a 20 mg dose may have their dose lowered to 10 mg for a trial period. If symptoms recur, increase the dosage to 20 mg every 4 wk. Doses higher than 30 mg are not recommended. Patients with carcinoid tumors and VIPomas who experience periodic exacerbation of symptoms, whether they are being maintained on the immediate-release or long-acting depot formulation, may be given subcutaneous immediate-release injections for a few days at the dosage they were receiving prior to switching to the depot formulation. When symptoms are controlled, the subcutaneous injections may be discontinued.

SIDE EFFECTS

* Most people do not experience all of the side effects listed.
* Side effects are often predictable in terms of their onset and duration.
* Side effects are almost always reversible and will go away after treatment is complete.
* There are many options to help minimize or prevent side effects.
* There is no relationship between the presence or severity of side effects and the effectiveness of the medication.
* The side effects of octreotide Acetate and their severity depend on how much of the drug is given and which preparation is given. In other words, high doses may produce more severe side effects.

The following side effects are common

Gallstones (common with long term use but rarely symptomatic enough to require intervention).
Nausea
Pain at the injection site

These side effects are less common

* Abdominal Pain
* Flatulence (gas)
* Constipation
* Vomiting
* Diarrhea (may be due to the disease rather than the medication)
* Upper respiratory infection (see lung problems)
* Fatigue
* Flu-like syndrome
* Dizziness
* Headache
* If you have diabetes, your blood sugar levels may be affected. Discuss this with your healthcare provider, how you will monitor your blood sugar readings at home.
* You may experience a slower heartbeat

PRECAUTIONS

Before starting octreotide treatment, make sure you tell your doctor about any other medications you are taking (including prescription, over-the-counter, vitamins, herbal remedies, etc.). Do not take aspirin, or products containing aspirin unless your doctor specifically permits this.
Inform your health care professional if you are pregnant or may be pregnant prior to starting this treatment. Pregnancy category B (there is no evidence of risk in humans based on negative animal studies. Use in pregnancy only if clearly needed). For both men and women: Do not conceive a child (get pregnant) while taking octreotide. Barrier methods of contraception, such as condoms, are recommended
Do not breast feed while taking this medication.

Although the degree to which these abnormalities are related to octreotide Acetate therapy is not clear, new abnormalities of glycemic control, thyroid function and ECG developed during octreotide Acetate therapy as described below.

Risk of Pregnancy with Normalization

In patients with concomitant Type I diabetes mellitus, octreotide Acetate Injection and octreotide Acetate LAR® Depot (octreotide acetate for injectable suspension) are likely to affect glucose regulation, and insulin requirements may be reduced. Symptomatic hypoglycemia, which may be severe, has been reported in these patients. In non-diabetics and Type II diabetics with partially intact insulin reserves, octreotide Acetate Injection or octreotide Acetate LAR Depot administration may result in decreases in plasma insulin levels and hyperglycemia. It is therefore recommended that glucose tolerance and antidiabetic treatment be periodically monitored during therapy with these drugs.Several cases of pancreatitis have been reported in patients receiving octreotide Acetate therapy.octreotide Acetate may alter absorption of dietary fats in some patients.Acromegaly: Growth Hormone, IGF-I (somatomedin C) Responsiveness to octreotide Acetate may be evaluated by determining growth hormone levels at 1-4 hour intervals for 8-12 hours post dose. Alternatively, a single measurement of IGF-I (somatomedin C) level may be made two weeks after drug initiation or dosage change.Carcinoid: 5-HIAA (urinary 5-hydroxyindole acetic acid), plasma serotonin, plasma Substance P. Nursing Mothers

DRUG DESCRIPTION

The acetate salt of a synthetic long-acting cyclic octapeptide with pharmacologic properties mimicking those of the natural hormone somatostatin. Octreotide is a more potent inhibitor of growth hormone, glucagon, and insulin than somatostatin. Similar to somatostatin, this agent also suppresses the luteinizing hormone response to gonadotropin-releasing hormone, decreases splanchnic blood flow, and inhibits the release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, pancreatic polypeptide, and thyroid stimulating hormone.Octreotide is hormone drug that is used to treat some types of cancer. This medication is classified as an somatostatin analog.This medicine is given to control symptoms such as diarrhea or flushing in patients with tumors such as carcinoid, pancreatic islet cell tumors, gastrinoma, or vasoactive intestinal peptide-secreting tumorst is also used to treat acromegaly, when the body produces too much growth hormone, and the hands, feet, face or head grow too large

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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Taj Pharmaceuticals Limited,
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