

Octreotide Depot [®]

Octreotide (as acetate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Octreotide Depot. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Octreotide Depot against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Octreotide Depot is used for

Octreotide Depot is a long acting form of octreotide injection. It is injected into the buttocks once every 4 weeks, instead of having frequent injections of the octreotide under the skin.

- Octreotide Depot is used to treat acromegaly

In people with acromegaly the body makes too much growth hormone which controls the growth of tissues, organs and bones. Too much growth hormone leads to enlargement of the bones, especially of the hands and feet. Other symptoms include headaches, increased sweating, tiredness, numbness of the hands and feet, pain and stiffness in the joints and loss of sexual function. By blocking the excess growth hormone,

Octreotide Depot can relieve many of these symptoms.

- Octreotide Depot is used to relieve symptoms of certain types of cancer such as carcinoid tumour and VIPoma.

By blocking hormones that are over-produced in these conditions, Octreotide Depot can relieve symptoms such as flushing of the skin and severe diarrhoea. Octreotide Depot contains octreotide, a man-made medicine derived from somatostatin. Somatostatin is a substance found in the human body which controls the effects of certain hormones such as insulin and growth hormone. Octreotide Depot is used instead of somatostatin because its effects are stronger and last longer.

- Octreotide Depot is used to treat advanced neuroendocrine tumours located in the gut (eg appendix, small intestine or colon).

Neuroendocrine tumours are rare tumours which can be found in different parts of the body.

Octreotide Depot is also used to control the growth of these tumours, when they are located in the gut (eg appendix, small intestine or colon).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is very little information on the use of this medicine in children.

Before you have Octreotide Depot

When you must not take it

Do not take Octreotide Depot if you have an allergy to:

- octreotide (the active ingredient in Octreotide Depot) or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have or have had any of the following medical conditions:

- gallstones now or in the past or experience any complications like fever, chills, abdominal pain, or yellowing of your skin or eyes as prolonged use of Octreotide Depot may result in gallstone formation
- problems with your blood sugar levels, either too high (diabetes) or too low (hypoglycaemia)
- problems with your liver
- a history of vitamin B12 deprivation

- problems with your blood pressure
- problems with your thyroid

Your doctor may want to take special precautions if you have any of these conditions.

Tell your doctor if you are taking other medicines to control blood pressure (beta-blockers or calcium channel blockers) or agents to control fluid and electrolyte balance.

Dose adjustment may be necessary.

Tell your doctor if you are pregnant or plan to become pregnant or wish to breast-feed your baby.

There is not much information on the use of Octreotide Depot during pregnancy or breast-feeding. If it is necessary for you to have this medicine, your doctor will discuss with you the benefits and risks involved. They may recommend that you use a method of contraception to prevent pregnancy during your treatment. It is not known if Octreotide Depot passes into breast milk. Breastfeeding is not recommended during treatment with Octreotide Depot.

If you have not told your doctor about any of the above, tell him/her before you start taking Octreotide Depot.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Octreotide Depot may interfere with each other. These include:

- bromocriptine, a medicine which is also used to treat acromegaly
- medicines for diabetes
- cimetidine, a medicine for ulcers
- cyclosporin, a medicine used to suppress the immune system

- quinidine, a medicine used to prevent irregular heartbeats
- medicines to control blood pressure (beta-blockers or calcium channel blockers)
- agents to control fluid and electrolyte balance

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Octreotide Depot is given

Your doctor or nurse will inject Octreotide Depot into your buttocks.

How much is given

The usual starting dose of Octreotide Depot is 20 mg, injected every 4 weeks. After about 3 months, the dose may be lowered to 10 mg or increased to 30 mg depending on how you respond to it.

Depending on your condition you may also need to continue injecting octreotide under the skin for about 2 weeks after your first injection of Octreotide Depot. Your doctor will tell you if this is the case.

If you receive Octreotide Depot for the treatment of neuroendocrine tumours located in the gut, the usual dose is 30 mg every 4 weeks. Your doctor will decide how long you should be treated with Octreotide Depot.

If you forget to have it

If you forget to have your injection, have it as soon as you remember and then go back to your normal schedule.

It will not do any harm if your dose is a few days late but some of your symptoms may come back temporarily until you get back on schedule.

If you are given too much (overdose)

Tell your doctor if you notice any of the following signs that the dose of Octreotide Depot is too high.

Some of the symptoms of an Octreotide Depot overdose may include hot flushes, fatigue, depression (sad mood), anxiety, lack of concentration and needing to pass water more frequently than usual.

If you are taking short acting octreotide injected under the skin, overdose symptoms may include changes in heartbeat, dizziness, light headedness, severe radiating chest pain, change in attention, uncoordinated movement, pain under the rib cage (right side), distended stomach, yellowing of the skin and eyes, fever, severe upper stomach pain with nausea and vomiting, diarrhoea, weakness, feeling lethargic, weight loss, stomach pain and discomfort, brown coloured urine and clay-coloured stools, nausea, weakness.

No life-threatening reactions have been reported after an overdose of this medicine.

While you are having Octreotide Depot

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

If you must have this medicine for a long time, your doctor may want to check your blood sugar, gallbladder, thyroid and liver function from time to time to prevent unwanted side effects from happening.

If your doctor recommends it, make sure you use a method of contraception to prevent pregnancy during your treatment. Tell your doctor if you become pregnant while you are receiving this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Octreotide Depot.

Tell any other doctor, dentist or pharmacist who treats you that you are having Octreotide Depot.

Things you must not do

Do not give your medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Octreotide Depot affects you.

This medicine may cause dizziness, light-headedness or weakness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Octreotide Depot.

All medicines can cause side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue

or other part of the body; shortness of breath, wheezing or troubled breathing

- severe pain, tenderness or swelling in the stomach or abdomen, which may be accompanied by fever, nausea and vomiting, yellowing of the skin and eyes, loss of appetite, generally feeling unwell, itching, light coloured urine (symptoms of a possible problem with your liver, pancreas or gall bladder)
- symptoms of low blood glucose (hypoglycaemia), including sweating, trembling, dizziness, weakness, hunger, palpitations (feeling of fast or irregular heartbeat) and fatigue
- symptoms of high blood glucose (hyperglycaemia), including lethargy or tiredness, headache, thirst, passing large amounts of urine, and blurred vision
- symptoms of changes in the activity of the thyroid gland (hyper or hypothyroidism) including changes in heart rate, appetites or weight, tiredness, feeling cold or sweating too much, anxiety or swelling at the front of the neck.
- unusually slow or fast heartbeat.
- thirst, low urine output, dark urine, dry flushed skin
- increased bleeding or bruising (could be low level of platelets in blood).

Tell your doctor if you notice any of the following side effects and they worry you:

- pain, irritation, redness, rash or swelling at the injection site
- loss of appetite
- indigestion, nausea or vomiting
- cramps
- feeling of bloating or wind
- constipation, diarrhoea or other change in bowel motions
- abdominal pain
- headache
- temporary hair loss

- changes in the rhythm of your heartbeat
- shortness of breath
- weakness

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Octreotide Depot

Storage

If you have to store Octreotide Depot at home:

- Keep the vials in the original container until it is time to use them.
- If you are storing the vials for longer than one day, keep them in the refrigerator at 2°C to 8°C. Do not freeze them.
- You can remove Octreotide Depot from the fridge and store it below 25°C on the day of injection but it must be kept in the original outer carton to protect it from light. The suspension must only be prepared immediately prior to injection.
- Octreotide Depot carton contents should reach room temperature (20°C to 25°C) before preparation. A minimum of 30 minutes is required.

If any vials have been left out of the fridge for longer than one day (24 hours), do not use them.

The reconstituted suspension contains no preservative.

This medicine is for single use in one patient only.

Discard any residue.

Keep the medicine where children cannot reach it.

Disposal

If your doctor stops your treatment with this medicine or the expiry date has passed or the vials have been left out of the fridge for too long, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Octreotide Depot is a white to white with yellowish tint powder packed in a glass vial. The diluent is a clear, colourless to slightly yellow or brown solution. Each box of Octreotide Depot contains one vial of powder, a glass syringe of diluent to mix with the powder, a vial adaptor and safety injection needle.

Ingredients

Octreotide Depot vials contain 10 mg, 20 mg or 30 mg of the active ingredient octreotide (as acetate). They also contain:

- mannitol
- polyglactin

The solution in the syringe contains:

- carmellose sodium
- mannitol
- poloxamer
- water for injections

Sponsor

Octreotide Depot is supplied in Australia by:

Teva Pharma Australia Pty Ltd
37 Epping Road
Macquarie Park NSW 2113
AUSTRALIA

Teva Pharma (New Zealand) Ltd
Level 14, 41 Shortland Street
Auckland 1010

NEW ZEALAND

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Australian Registration Numbers

Octreotide Depot 10 mg vial
AUST R 321280

Octreotide Depot 20 mg vial
AUST R 321282

Octreotide Depot 30 mg vial
AUST R 321281