

OCTREOTIDE-MAXRX INJECTION

octreotide acetate

What is in this leaflet

This leaflet answers some common questions about Octreotide-MaxRx Injection. 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 using Octreotide-MaxRx Injection against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Octreotide-MaxRx Injection is used for

Octreotide-MaxRx Injection has three uses:

1. Octreotide-MaxRx Injection 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. This 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-MaxRx Injection can relieve many of these symptoms.

2. Octreotide-MaxRx Injection is used to relieve symptoms of certain types of cancer such as carcinoid syndrome and VIPoma. By blocking hormones that are over-produced in these conditions, Octreotide-MaxRx Injection can relieve symptoms such as flushing of the skin and severe diarrhoea.
3. Octreotide-MaxRx Injection is used for people who are having surgery on the pancreas. This medicine helps to lower the chance of complications after the surgery.

Octreotide-MaxRx Injection contains octreotide, a man-made medicine derived from somatostatin, a substance found in the human body. Octreotide is used instead of somatostatin because its effects are stronger and last longer so that it needs to be given only 2 or 3 times a day.

Ask your doctor if you have any questions about why Octreotide-MaxRx Injection has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

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

Before you take Octreotide-MaxRx Injection

When not to take it

Do not use Octreotide-MaxRx Injection if you have an allergy to:

- Octreotide (the active ingredient in Octreotide-MaxRx Injection) 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 use Octreotide-MaxRx Injection after the expiry date printed on the

pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

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

- gallstones;
- problems with your blood sugar levels, either too high (diabetes) or too low (hypoglycaemia);
- problems with your liver.

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

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

There is not much information on the use of Octreotide-MaxRx Injection during pregnancy or breast-feeding. If it is necessary for you to use this medicine, your doctor will discuss with you the benefits and risks involved.

If you have not told your doctor about any of these things, tell him/her before you use Octreotide-MaxRx Injection.

Taking other medicines

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

Some medicines and Octreotide-MaxRx Injection may interfere with each other.

Some of these medicines 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.

You may need to take 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 using Octreotide-MaxRx Injection.

How to take Octreotide-MaxRx Injection

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The dose of Octreotide-MaxRx Injection depends on the condition being treated.

1. Acromegaly: treatment is usually started with injections of 0.05 to 0.1

mg every 8 or 12 hours. The dose can then be adjusted depending on how well it blocks growth hormone and relieves symptoms such as tiredness, sweating and headache.

2. Carcinoid syndrome and VIPoma: treatment is usually started with injections of 0.05 mg once or twice a day. The dose can be increased if symptoms such as diarrhoea are not relieved.
3. Surgery on the pancreas: injections of 0.1 mg are usually given three times a day for one week, starting about an hour before the operation.

How to take it

Octreotide-MaxRx Injection cannot be taken by mouth because it is rapidly broken down in the stomach. Instead it is given as a subcutaneous injection. That means that it is injected into the fat layer just under the skin.

If you are giving the injections yourself

If you will be giving the injections yourself, your doctor or nurse will teach you how to do it properly.

Before using a Octreotide-MaxRx Injection ampoule, check the liquid for particles or a change in colour. If you notice anything unusual, do not use the ampoule.

Once an ampoule is opened, use it immediately and throw out any liquid that remains.

The ampoule does not contain any preservative.

Give the injections between meals or at bedtime. Avoid having meals around the time of the injections.

This will help to reduce the chance of stomach upset.

To help prevent irritation or pain at the injection site:

- Choose a new site for each injection. The upper arms, thighs and abdomen are good areas for injection.
- Make sure the ampoule is at room temperature before you use it. If it has been in the fridge, take it out half an hour before using it. You can warm it up in your hand but don't try to heat it.

If you notice pain, stinging, tingling, burning, redness or swelling at the injection site after the injection, gently rub the site for a few seconds.

These side effects rarely last more than 15 minutes after an injection.

If you take too much

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that an overdose has happened. Do this even if there are no signs of discomfort or poisoning.

Some of the symptoms of an overdose may include slow heartbeat, flushing of the face, cramps in the abdomen, diarrhoea, an empty feeling in

the stomach and nausea (feeling sick).

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

While you are taking Octreotide-MaxRx Injection

Things you must do

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

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Octreotide-MaxRx Injection.

Tell any other doctor, dentist or pharmacist who treats you that you are using Octreotide-MaxRx Injection.

If you forget to take it

Inject the dose as soon as you remember, and then go back to using it as you would normally.

It won't do any harm if you miss a dose but some of your symptoms may come back temporarily until you get back on schedule.

Do not use a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

Things you must not do

Do not give this 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-MaxRx Injection affects you.

This medicine may cause dizziness, lightheadedness 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 using Octreotide-MaxRx Injection.

All medicines can have 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 this list of possible 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 or go to Accident and Emergency at your nearest hospital if you notice:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts 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 (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;
- unusually slow heartbeat.

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

- irritation or pain at the injection site;
- loss of appetite;
- nausea or vomiting;
- cramps;
- feeling of bloating or wind;

- diarrhoea or other change in bowel motions;
- dizziness or light headedness;
- swelling of hands or feet due to excess fluid;
- tiredness or weakness;
- flushing of the skin;
- temporary hair loss.

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.

How to store Octreotide-MaxRx Injection

Storage

- Keep the ampoules in the original container until it is time to use them.
- You can store the ampoules for up to 2 weeks at room temperature.
- If you are storing the ampoules for longer than 2 weeks, keep them in the refrigerator. Do not freeze them.
- Do not store Octreotide-MaxRx Injection or any other medicine in the bathroom or near a sink.
- Do not leave them in the car or on window sills.

Keep the medicine where children cannot reach it.

Disposal

If any ampoules have been left out of the fridge for longer than 2 weeks, do not use them.

If your doctor tells you to stop using this medicine or you find that the expiry

date has passed or the ampoules 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 Octreotide-MaxRx Injection tablets look like

Octreotide-MaxRx Injection comes in 1 mL glass ampoules containing a clear, colourless liquid; boxes of 5 ampoules.

Ingredients

Octreotide-MaxRx Injection ampoules contain 0.05 mg, 0.1 mg or 0.5 mg of the active ingredient, octreotide (as octreotide acetate).

They also contain:

- glycine
- mannitol
- hydrochloric acid
- water for injections

Sponsor

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell, VIC, 3124
Australia

Australian Registration Numbers

Octreotide-MaxRx Injection
0.05 mg ampoule AUST R
148404

Octreotide-MaxRx Injection
0.1 mg ampoule AUST R
148402

Octreotide-MaxRx Injection
0.5 mg ampoule AUST R
148403

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