

OCTREOTIDE SUN

Octreotide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Octreotide SUN. The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware. 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 SUN 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 SUN is used for

Octreotide SUN has three uses:

1. Octreotide SUN 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 SUN can relieve many of these symptoms.

2. Octreotide SUN 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 SUN can relieve symptoms such as flushing of the skin and severe diarrhoea.

3. Octreotide SUN is used for people who are having surgery on the pancreas. This medicine helps to lower the chance of complications after the surgery.

Octreotide SUN 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 SUN 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 use Octreotide SUN

When you must not use it

Do not use Octreotide SUN if you have an allergy to:

- octreotide (the active ingredient in Octreotide SUN) 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 SUN 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
- diabetes, as Octreotide SUN can affect blood sugar levels. If you are diabetic, your sugar levels should be checked regularly
- problems with your liver
- a history of vitamin B 12 deprivation

Your doctor may want to take special precautions if you have any of the above 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 intend to become pregnant or wish to breast-feed your baby.

There is not much information on the use of Octreotide SUN 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. They may recommend that you use a method of contraception to prevent pregnancy during your treatment. It is not known if Octreotide SUN passes into breast milk. Breastfeeding is not recommended during treatment with Octreotide SUN.

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

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 SUN 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 SUN.

How to use Octreotide SUN

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 it is given

Octreotide SUN 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.

How much is given

The dose of Octreotide SUN 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.

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 an Octreotide SUN 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 forget to use 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.

If you use too much (Overdose)

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 hot flushes, fatigue, depression (sad mood), anxiety, lack of concentration and needing to pass water more frequently than usual.

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

While you are using Octreotide SUN

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, thyroid and liver functions 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 using Octreotide SUN.

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

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 SUN 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 SUN.

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, 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
- unusually slow or fast heartbeat

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
- headache
- dizziness or light headedness
- swelling of hands or feet due to excess fluid
- tiredness or weakness
- flushing of the skin
- temporary hair loss
- changes in the rhythm of your heartbeat
- shortness of breath
- 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.

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 SUN

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.
- For longer than 2 weeks, keep them in the refrigerator. Do not freeze them.
- Do not store Octreotide SUN 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 it looks like

Octreotide SUN comes in 1 mL glass ampoules containing a clear, colourless liquid; boxes of 5

Ingredients

Octreotide SUN ampoules contain 0.05 mg, 0.1 mg or 0.5 mg of the active ingredient, octreotide (as octreotide acetate). They also contain:

- (S)-lactic acid
- Mannitol
- Sodium bicarbonate
- Water for injection

Sponsor:

Ranbaxy Australia Pty Ltd
(A Sun Pharma Company)
Macquarie Park
Sydney NSW 2113

Australian registration numbers:

Octreotide SUN 50 microgram/1mL (i.e. 0.05 mg/1mL): 297815

Octreotide SUN 100 microgram/1mL (i.e. 0.1 mg/1mL): 297814

Octreotide SUN 500 microgram/1mL (i.e. 0.5 mg/1mL): 297813

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