Sandostatin® LAR®

Octreotide (as acetate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sandostatin LAR.

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. You can also download the most up to date leaflet from www.novartis.com.au.

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 having Sandostatin LAR against the benefits they expect it will give you.

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

Keep this leaflet.

You may need to read it again.

What Sandostatin LAR is used for

Sandostatin LAR is a long acting form of Sandostatin injection. It is injected into the buttocks once every 4 weeks, instead of having frequent injections of the short-acting Sandostatin under the skin.

- Sandostatin LAR 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, Sandostatin LAR can relieve many of these symptoms.

- Sandostatin LAR 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, Sandostatin LAR can relieve symptoms such as flushing of the skin and severe diarrhoea.

Sandostatin LAR 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. Sandostatin LAR is used instead of somatostatin because its effects are stronger and last longer.

- Sandostatin LAR 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. Sandostatin LAR 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 Sandostatin LAR 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 have Sandostatin LAR

When you must not have it

Do not have Sandostatin LAR if you have an allergy to:

- octreotide (the active ingredient in Sandostatin LAR) 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 have Sandostatin LAR 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 have it

Tell your doctor if you have 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 Sandostatin LAR 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.
- problems with your pancreas

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

Your doctor may wish to check your pancreatic enzyme function.

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 Sandostatin LAR 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 Sandostatin LAR passes into breast milk. Breastfeeding is not recommended during treatment with Sandostatin LAR.

If you have not told your doctor about any of these things, tell him/her before you have Sandostatin LAR.

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 Sandostatin LAR 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
- medicines to control blood pressure (beta-blockers or calcium channel blockers)
- agents to control fluid and electrolyte balance

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 having Sandostatin LAR.

How Sandostatin LAR is given

Your doctor or nurse will inject Sandostatin LAR into your buttocks.

How much is given

The usual starting dose of Sandostatin LAR 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 short-acting Sandostatin under the skin for about 2 weeks after your first injection of Sandostatin LAR. Your doctor will tell you if this is the case.

If you receive Sandostatin LAR 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 Sandostatin LAR.

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 Sandostatin LAR is too high.

Some of the symptoms of an Sandostatin LAR 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 Sandostatin injected under the skin, overdose symptoms may include changes in heart-beat, 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 Sandostatin LAR

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 Sandostatin LAR.

Tell any other doctor, dentist or pharmacist who treats you that you are having Sandostatin LAR.

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 Sandostatin LAR 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 having Sandostatin LAR.

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 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 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 Sandostatin LAR

Storage

If you have to store Sandostatin LAR 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 Sandostatin LAR 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.

- Sandostatin LAR 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 you find that 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

Sandostatin LAR 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 Sandostatin LAR contains one vial of powder, a glass syringe of diluent to mix with the powder, a vial adaptor and safety injection needle.

Ingredients

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

- mannitol
- polyglactin glucose

The solution in the syringe contains:

- mannitol
- carmellose sodium
- poloxamer
- water for injections

Sponsor

Sandostatin LAR is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

Web site: www.novartis.com.au

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Sandostatin LAR 20 mg vial

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Sandostatin LAR 30 mg vial

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