

SIGNIFOR® LAR

pasireotide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIGNIFOR LAR. 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 this medicine against the benefits they expect it will provide.

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

Keep this leaflet with the medicine.

You may need to read it again.

What SIGNIFOR LAR is used for

SIGNIFOR LAR is a prescription medicine used to treat patients with acromegaly.

Acromegaly is caused by an enlargement in the pituitary gland (a gland at the base of the brain) called a pituitary adenoma. This leads the body to produce too much of a hormone called growth hormone (GH). This overproduction of GH causes the body to produce too much of another hormone called insulin-like growth factor-1 (IGF-1). Normally, these hormones control growth of tissues, organs and bones.

SIGNIFOR LAR is a medicine containing a synthetic substance called pasireotide that mimics the action of somatostatin, a substance

normally found in the human body, which can block the production of hormones such as GH and IGF-1.

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

SIGNIFOR LAR binds to somatostatin receptors which are present in high number in the brain in the pituitary gland where the excessive amount of growth hormone is produced. By binding to these somatostatin receptors, SIGNIFOR LAR reduces the production of GH and IGF-1 and may reduce the size of the adenoma.

Too much GH or IGF-1 leads to an increase in the size of bones and tissues, especially in the hands and feet.

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.

SIGNIFOR LAR is to be administered by the physician or healthcare professional only.

Before SIGNIFOR LAR is injected

When you must not take it

Do not take SIGNIFOR LAR if you have an allergy to pasireotide, the active ingredient, or to 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 if you suffer from severe liver disorder.

Do not take this medicine 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.

Do not use SIGNIFOR LAR if you notice the powder in the vial has changed its colour, or if you notice that the diluent is not clear or contains particles.

SIGNIFOR LAR is not to be used in children or adolescents.

Before starting SIGNIFOR LAR

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- problems with your blood glucose levels, either too high (hyperglycaemia/diabetes) or too low (hypoglycaemia).
- problems with your liver.
- a heart disorder or a heart rhythm disorder, such as an irregular heartbeat or an abnormal electrical signal called “prolongation of the QT interval, or QT prolongation”.
- low levels of potassium or magnesium in your blood.
- gallstones.

Tell your doctor or pharmacist immediately if you get any of

these symptoms during treatment with SIGNIFOR LAR.

Tell your doctor if you are taking, or have ever taken:

- medicines to control your heart rate (antiarrhythmics) or medicines that may have an unwanted effect on the function of the heart beat (QT prolongation).
- medicines to control your blood pressure (such as beta-blockers or calcium channel blockers) or agents to control electrolytes (potassium, magnesium) balance in your body.

Your doctor may want to take special precautions.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

SIGNIFOR LAR is not recommended during pregnancy. Your doctor will discuss with you the potential risk of taking SIGNIFOR LAR during pregnancy.

You should not breastfeed your child while using SIGNIFOR LAR. It is not known if SIGNIFOR LAR passes into breast milk.

Women of child-bearing potential should use an effective method of contraception during treatment. Ask your doctor about the need for contraception before you start taking SIGNIFOR LAR.

Your doctor will discuss with you the potential risks and benefits involved.

Taking other medicines

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

Some medicines and SIGNIFOR LAR may interfere with each other. These include:

Antiarrhythmics used to treat irregular heart rate such as:

- amiodarone

- disopyramide
- quinidine
- sotalol

Medicines that may have an unwanted effect on the function of the heart (QT prolongation) such as:

- ketoconazole
- chloroquine
- clarithromycin
- haloperidol
- methadone

Certain other medicines, such as:

- cyclosporin
- terfenadine
- bromocriptine

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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How SIGNIFOR LAR is given

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

The site of injections should be alternated between the left and right buttock.

How much is given

The recommended initial dose of SIGNIFOR LAR is 40 mg administered by deep intramuscular injection every 4 weeks.

If you have or had liver problems in the past your doctor may want to start your treatment with a lower initial dose of 20 mg of SIGNIFOR LAR every 4 weeks.

Depending on how you respond to the treatment with SIGNIFOR LAR your doctor may prescribe a higher or lower dose.

How long you will need to take this medicine

Continue taking SIGNIFOR LAR every 4 weeks for as long as your doctor tells you.

This is a long-term treatment, possibly lasting for years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. If you interrupt your treatment with SIGNIFOR LAR, your growth hormone (GH and IGF-1) levels may increase again and your symptoms may come back.

If you have questions about how long to take SIGNIFOR LAR, talk to your doctor or your pharmacist.

If you forget to have your injection

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)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SIGNIFOR LAR. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are having SIGNIFOR LAR

Things you must do

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

Your doctor may wish to monitor:

- your blood glucose levels and may need to start you on or adjust your anti-diabetic medication. Your doctor may also instruct you to self-monitor your blood glucose levels weekly for the first 3 months and periodically thereafter, as well as over the first 4-6 weeks after any dose increase. Poor control of your blood glucose levels even while you are receiving anti-diabetic therapy may increase your chances of developing severe hyperglycaemia during SIGNIFOR LAR therapy.
- your heart rate using a test called electrocardiogram or ECG. If you take a heart medication, your doctor may also need to adjust its dosage.
- your gallbladder, liver enzymes and pituitary hormones periodically.

If you become pregnant while taking this medicine, tell your doctor immediately.

It may affect your developing baby. Your doctor will discuss the risks and benefits of continuing treatment in this case.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to 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 SIGNIFOR LAR affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SIGNIFOR LAR even if you do not think it is connected with the medicine.

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 experience 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 any of the following serious side effects:

- High blood glucose level (you may experience excessive thirst, high urine output, increased appetite with weight loss, tiredness, nausea, vomiting, abdominal pain, fruity scented breath, trouble breathing and confusion).
- Low blood glucose.
- Gallstones (you may experience sudden back pain or pain on the right side of your abdomen).
- Slow heart rate.
- Irregular heart rate.
- Low cortisol levels (you may experience extreme weakness, weight loss, nausea, vomiting, low blood pressure).
- Bile flow from liver to intestine can be reduced (cholestasis).

The symptoms may include yellowing of the skin/eye, dark urine, pale stool and itching.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Diarrhoea
- Tiredness, fatigue, pale skin (signs of low level of red blood cells)
- Headache
- Change in glucose levels in blood
- Hair loss
- Abdominal pain
- Common cold
- Joint pain
- Back pain
- Abdominal expansion
- Bloating
- Nausea
- Dizziness
- Fatigue
- Vomiting
- Flu like symptoms
- Bronchitis
- Upper respiratory tract infection
- Pain, discomfort, itching and swelling at the injection site
- Pain in the extremities
- Flatulence (wind)
- Constipation
- Cough
- Loss of appetite
- Burning feeling when urinating and/or frequent or intense urge to urinate
- Weight decreased
- Muscle spasms
- Sore throat
- Fever or high temperature
- Inflammation of gallbladder with signs of upper abdominal pain (cholecystitis)
- Oily or fatty stools
- Discoloured stools

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects, for example, changes in liver function, blood sugar levels, pancreatic

function, abnormal blood test results can only be found when your doctor does tests from time to time to check your progress.

After using SIGNIFOR LAR

Storage

- Store at 2 - 8°C.
- Refrigerate. Do not freeze.

If you have to store SIGNIFOR LAR at home:

- Keep the medicine where children cannot reach it.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
- On the day of injection you can remove SIGNIFOR LAR from the fridge and let the carton contents stand at room temperature (below 25°C) for a minimum of 30 minutes before reconstitution, but do not exceed 24 hours.
- SIGNIFOR LAR suspension must only be prepared by a trained healthcare professional and prepared immediately before administration. They will also inject SIGNIFOR LAR into your buttock.
- This medicine contains no preservative and is for single use in one patient only. Discard any residue.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

SIGNIFOR LAR is supplied as a carton containing 1 x vial of powder, 1 x diluent in a prefilled syringe, 1 x safety injection needle and 1 x vial adaptor.

The powder is slightly yellowish to yellowish. The diluent is clear, colourless to slightly yellow to slightly brown solution. After reconstitution the suspension is homogenous, milky, and slightly yellowish to yellowish in appearance.

SIGNIFOR LAR powder is available in three vial strengths: 20 mg, 40 mg or 60 mg

Ingredients

SIGNIFOR LAR vials contain 20 mg, 40 mg or 60 mg of the active ingredient, pasireotide (as embonate). They also contain:

- Polyglactin glucose
- Polyglactin

The diluent in the prefilled syringe contains:

- Mannitol
- Carmellose sodium
- Poloxamer
- Water for injections

Sponsor

SIGNIFOR® LAR is supplied in Australia by:

Recordati Rare Diseases Australia Pty Ltd, Suite 1802, Level 18, 233 Castlereagh Street, Sydney, NSW, 2000 Australia
Phone: +61 (0) 408 061 403
rrdaustriainfo@recordati.com

Sponsor for Vial Adaptor

Emergo Asia Pacific Pty Ltd
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SIGNIFOR LAR 60 mg AUST R 225274

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