

# SIGNIFOR® LAR

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using SIGNIFOR® LAR?

SIGNIFOR®LAR contains the active ingredient pasireotide. SIGNIFOR®LAR is a prescription medicine used to treat patients with acromegaly.

For more information, see Section [1. Why am I using SIGNIFOR® LAR?](#) in the full CMI.

### 2. What should I know before I use SIGNIFOR® LAR?

Do not use if you have ever had an allergic reaction to pasireotide or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should I know before I use SIGNIFOR® LAR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SIGNIFOR®LAR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use SIGNIFOR® LAR?

- The recommended initial dose of SIGNIFOR®LAR is 40 mg administered by deep intramuscular injection every 4 weeks.
- Your doctor or nurse will inject SIGNIFOR®LAR into your buttocks. The site of injections should be alternated between the left and right buttock.
- More instructions can be found in Section [4. How do I use SIGNIFOR® LAR?](#) in the full CMI.

### 5. What should I know while using SIGNIFOR® LAR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or nurse you visit that you are using SIGNIFOR® LAR.</li><li>• Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.</li><li>• 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.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if their condition seems similar to yours.</li><li>• Do not use it to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how SIGNIFOR®LAR affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store at 2 - 8°C.</li><li>• Refrigerate. Do not freeze</li></ul>

For more information, see Section [5. What should I know while using SIGNIFOR® LAR?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Some of the serious side effects are high blood glucose level, low blood glucose, gall stones, slow heart rate, irregular heart rate, low cortisol levels and bile from the liver to intestine can be reduced.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# SIGNIFOR<sup>®</sup> LAR

Active ingredient(s): *pasireotide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SIGNIFOR<sup>®</sup> LAR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SIGNIFOR<sup>®</sup> LAR.**

**Where to find information in this leaflet:**

- [1. Why am I using SIGNIFOR<sup>®</sup> LAR?](#)
- [2. What should I know before I use SIGNIFOR<sup>®</sup> LAR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SIGNIFOR<sup>®</sup> LAR?](#)
- [5. What should I know while using SIGNIFOR<sup>®</sup> LAR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using SIGNIFOR<sup>®</sup> LAR?

**SIGNIFOR<sup>®</sup>LAR contains the active ingredient pasireotide.** SIGNIFOR<sup>®</sup>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<sup>®</sup>LAR is used instead of somatostatin because its effects are stronger and last longer. SIGNIFOR<sup>®</sup>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<sup>®</sup>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<sup>®</sup>LAR is to be administered by the physician or healthcare professional only.

**SIGNIFOR<sup>®</sup>LAR is 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.

## 2. What should I know before I use SIGNIFOR<sup>®</sup> LAR?

### Warnings

- **Do not use SIGNIFOR<sup>®</sup>LAR if you are allergic to pasireotide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.**
- **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.**
- **Do not use SIGNIFOR<sup>®</sup>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.**

### Children/Adolescents.

SIGNIFOR<sup>®</sup>LAR is not to be used in children or adolescents.

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.

**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 have allergies to any other medicines, foods, preservatives or dyes.**

**Check with your doctor if you:**

- 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.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

### **3. What if I am taking other medicines?**

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

Some medicines may interfere with SIGNIFOR®LAR and affect how it works. 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SIGNIFOR®LAR.**

### **4. How do I use SIGNIFOR® LAR?**

#### **How much to use**

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 use this medicine**

Continue using 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 use SIGNIFOR®LAR**

**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 it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.**

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

#### **If you use too much SIGNIFOR® LAR**

If you think that you have used too much SIGNIFOR® LAR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**)  
New Zealand: **0800 POISON** or **0800764766**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

**Keep the telephone numbers for these places handy.**

## 5. What should I know while using SIGNIFOR® LAR?

### Things you should 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 should 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.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how SIGNIFOR®LAR affects you.

### Looking after your medicine

#### 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.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

### When to discard your medicine

**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.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal System</b> <ul style="list-style-type: none"><li>• Diarrhoea</li><li>• Abdominal pain</li><li>• Abdominal expansion</li><li>• Bloating</li><li>• Nausea</li><li>• Vomiting</li><li>• Flatulence (wind)</li><li>• Constipation</li><li>• Oily or fatty stools</li><li>• Discoloured stools</li><li>• Loss of appetite</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<p><b>Hematological System</b></p> <ul style="list-style-type: none"> <li>Tiredness, fatigue, pale skin (signs of low level of red blood cells)</li> </ul> <p><b>Endocrine System</b></p> <ul style="list-style-type: none"> <li>Change in glucose levels in blood</li> </ul> <p><b>Skin and Hair</b></p> <ul style="list-style-type: none"> <li>Hair loss</li> </ul> <p><b>Musculoskeletal System</b></p> <ul style="list-style-type: none"> <li>Joint pain</li> <li>Back pain</li> <li>Pain in the extremities</li> <li>Muscle spasms</li> </ul> <p><b>Respiratory System</b></p> <ul style="list-style-type: none"> <li>Common cold</li> <li>Upper respiratory tract infection</li> <li>Cough</li> <li>Sore throat</li> <li>Bronchitis</li> </ul> <p><b>Nervous System</b></p> <ul style="list-style-type: none"> <li>Headache</li> <li>Dizziness</li> <li>Fatigue</li> </ul> <p><b>Genitourinary System</b></p> <ul style="list-style-type: none"> <li>Burning feeling when urinating and/or frequent or intense urge to urinate</li> </ul> <p><b>General/Systemic</b></p> <ul style="list-style-type: none"> <li>Pain, discomfort, itching and swelling at the injection site</li> <li>Weight decreased</li> <li>Flu like symptoms</li> <li>Fever or high temperature</li> </ul>	
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<ul style="list-style-type: none"> <li>Low cortisol levels (you may experience extreme weakness, weight loss, nausea, vomiting, low blood pressure)</li> </ul> <p><b>Cardiovascular System</b></p> <ul style="list-style-type: none"> <li>Slow heart rate.</li> <li>Irregular heart rate.</li> </ul> <p><b>Gastrointestinal System</b></p> <ul style="list-style-type: none"> <li>Gallstones (you may experience sudden back pain or pain on the right side of your abdomen).</li> <li>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</li> <li>Inflammation of gallbladder with signs of upper abdominal pain (cholecystitis)</li> </ul>	<p><b>these serious side effects.</b></p>
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

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.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

### Serious side effects

Serious side effects	What to do
<p><b>Endocrine System</b></p> <ul style="list-style-type: none"> <li>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)</li> <li>Low blood glucose.</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of</b></p>

## 7. Product details

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

### What SIGNIFOR®LAR contains

<p><b>Active ingredient (main ingredient)</b></p>	<p>pasireotide (as embonate)</p> <p>SIGNIFOR®LAR vials contain 20 mg, 40 mg or 60 mg of the active ingredient, pasireotide (as embonate)</p>
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<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>· Polyglactin glucose</li> <li>· Polyglactin</li> </ul> <p>The diluent in the prefilled syringe contains:</p> <ul style="list-style-type: none"> <li>· Mannitol</li> <li>· Carmellose sodium</li> <li>· Poloxamer</li> <li>· Water for injections</li> </ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

### What SIGNIFOR®LAR 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

Australian Registration Numbers:

SIGNIFOR®LAR 20 mg AUST R 225272

SIGNIFOR®LAR 40 mg AUST R 225273

SIGNIFOR®LAR 60 mg AUST R 225274

### Who distributes SIGNIFOR®LAR

#### AUSTRALIA

Recordati Rare Diseases Australia Pty Ltd

Level 10

100 Arthur Street

North Sydney

NSW 2060

Australia

Phone: +61 (0) 408 061 403

rrdaustrialiainfo@recordati.com

#### Vial Adaptor

Emergo Asia Pacific Pty Ltd

T/a Emergo Australia

Level 20 Tower II Darling Park 201

Sussex Street S

YDNEY, NSW, 2000

#### Hypodermic Safety Needle

Cardinal Health Australia 503 Pty Ltd

TMF Corporate Services Aust Pty Limited, Suite 1 Level 11  
66 Goulburn Street,  
Sydney, NSW, 2000 Australia

#### **NEW ZEALAND**

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks, Mangere

Mt. Wellington,

New Zealand

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This leaflet was prepared in January 2026.

Australia

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