

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®?

SIGNIFOR® contains the active ingredient pasireotide. SIGNIFOR® is used to treat Cushing's Disease, a condition caused by an enlargement in the pituitary gland (pituitary adenoma, a benign tumour) which produces too much of a hormone called adrenocorticotrophic hormone (ACTH).

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

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

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.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SIGNIFOR® 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®?

Your doctor or nurse will instruct you on how to inject yourself with SIGNIFOR®.

Follow all directions given to you by your doctor or nurse. They may differ from the information contained in this leaflet.

If you have any questions, contact your doctor, nurse or pharmacist.

More instructions can be found in Section [4. How do I use SIGNIFOR®?](#) in the full CMI.

5. What should I know while using SIGNIFOR®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SIGNIFOR®.• Keep all of your doctor's appointments so that your progress can be checked.• If you become pregnant while taking this medicine, tell your doctor immediately• If you experience extreme weakness, weight loss, nausea, vomiting and low blood pressure seek urgent medical attention
Things you should not do	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how SIGNIFOR® affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool, dry place below 30°C.

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

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® even if you do not think it is connected with the medicine. 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®

Active ingredient(s): *pasireotide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SIGNIFOR®. **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®.**

Where to find information in this leaflet:

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

1. Why am I using SIGNIFOR®?

SIGNIFOR® contains the active ingredient pasireotide.

Pasireotide is a synthetic substance that mimics the action of somatostatin, a substance normally found in the human body, which can block the production of certain hormones such as ACTH. The advantage of pasireotide over somatostatin is that its effect is stronger and lasts longer.

SIGNIFOR® is used to treat Cushing's Disease, a condition caused by an enlargement in the pituitary gland (pituitary adenoma, a benign tumour) which produces too much of a hormone called adrenocorticotrophic hormone (ACTH).

This overproduction of ACTH causes the body to produce too much of another hormone called cortisol. Too much cortisol leads to a variety of signs and symptoms such as weight gain with abdominal obesity, moon-shaped face, easy bruising, menstrual abnormalities, excessive body and facial hair, muscle wasting with generalized weakness and tiredness, depression and decreased libido. SIGNIFOR® is designed to block the production of ACTH and therefore cortisol and help to reduce the symptoms caused by excess of cortisol.

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.

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

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

Warnings

- Do not use SIGNIFOR® 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.**

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 (hyperglycemia/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 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)
- control your blood pressure (such as beta-blockers or calcium channel blockers) or agents to control electrolytes (potassium, magnesium) balance in your body

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

You should not breastfeed your child while using SIGNIFOR®. It is not known if SIGNIFOR® 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®.

3. What if I am 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® may interfere with each other. These include:

Anti-arrhythmics used to treat irregular heart rate such as:

- amiodarone
- disopyramide
- procainamide
- sotalol
- quinidine

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

- ketoconazole
- chloroquine
- halofantrine
- clarithromycin
- haloperidol
- methadone
- bepridil
- pimozone

Certain other medicines, such as:

- cyclosporin
- terfenadine
- bromocriptine

You may need to take different medicines. Your doctor and pharmacist have more information.

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

4. How do I use SIGNIFOR®?

How much to use

- The recommended dosage range of SIGNIFOR® is 300 to 900 micrograms (mcg) injected under the skin (subcutaneous)
- If you have high blood glucose levels or liver problems before you start using SIGNIFOR®, your doctor may want to start your treatment with a lower dose two times a day.
- Your doctor will monitor how you respond to the treatment with SIGNIFOR® and may ask you to change to a higher or lower dose.

When to use SIGNIFOR®

SIGNIFOR® should be used two times a day (approximately every 12 hours).

How to inject SIGNIFOR®

Your doctor or nurse will instruct you on how to inject yourself with SIGNIFOR®. Follow all directions given to you by your doctor or nurse.

They may differ from the information contained in this leaflet.

If you have any questions, contact your doctor, nurse or pharmacist.

This medicine comes in an ampoule i.e. a small glass container. Your doctor or nurse will have instructed you on how to use SIGNIFOR® ampoules. However before using the ampoule, please read the following instructions carefully. If you are not sure about how to give the injection or you have any questions, please ask your doctor or nurse for help.

The injection can be prepared using either two different needles to draw up and inject the solution or one short fine injection needle for both steps. Based on the local clinical practice, your doctor or nurse will tell you which method to use. Please follow their instructions.

Store SIGNIFOR® ampoules according to the storage condition listed at the bottom of this leaflet.

Important Safety Information

Always use new disposable needles and syringes every time you give yourself an injection.

Use syringes and needles only once. NEVER share needles and syringes with someone else.

Carefully inspect the ampoule prior to use. DO NOT USE if it is broken or if the liquid looks cloudy, coloured or contains particles. In all these cases, return the entire pack to the pharmacy.

For sterility reasons, ampoules should be opened just prior to administration.

This medicine is for single use in one patient only. Discard any residue.

SIGNIFOR® is intended for subcutaneous use. This means that it is injected through a short needle into the fatty tissue just under the skin.

The injection site is the place on your body where you are going to give yourself the injection.

The TOP OF THIGHS and the ABDOMEN are recommended areas for subcutaneous injection. It is important to rotate the site of your injections, that is, you should choose a different site each time you inject.

You should also avoid injections at sites that are sore, where the skin is irritated, the navel, waistline, bruises and scars.

To reduce local discomfort, it is recommended that the solution should be at room temperature before injection.

Do not inject SIGNIFOR® solution for injection into a vein or muscle.

PREPARING A DOSE

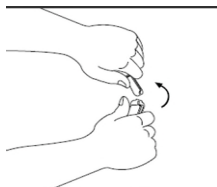
1. Wash your hands thoroughly with soap and water.
2. Take ampoule out of the box and carefully inspect the ampoule (as above).
3. Read the label first. Check the dose on the ampoule is the dose your doctor has prescribed for you.
4. SIGNIFOR® solution for injection is filled in a break-off ampoule. The coloured dot on the top part marks the position of the breaking point on the neck of the ampoule.



TAP the ampoule with your finger in order to make sure there is no liquid in the top part when you open the ampoule.

5. Recommended procedure:

Hold the ampoule in an upright position with the coloured dot facing away from you. Hold the base of the ampoule in one hand. Keeping your thumbs together above and below the neck, break off the top of the ampoule at the breaking point.



Once the ampoule is open, put it upright on a clean, flat surface.

6. Take the sterile syringe and attach the needle to it.
If you have been told to use two needles, you should use the long thick blunt drawing up needle for this step.



Before you proceed to the next step, clean the injection site with an alcohol wipe or similar.

7. Remove the cover from the needle. Put the needle into the ampoule and pull the plunger to draw up the entire contents of the ampoule into the syringe.



If you have been told to use two needles, you should now replace the long needle with the short giving needle.

8. Hold the syringe in one hand between two fingers with your thumb at the bottom of the plunger. Tap the syringe with your fingers to get rid of air bubbles. Make sure there is no air bubble in the syringe by pressing the plunger until the first drop appears on the tip of the needle.



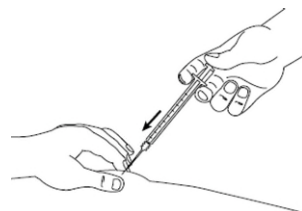
Do not let the needle touch anything. You are now ready to inject.

INJECTING A DOSE

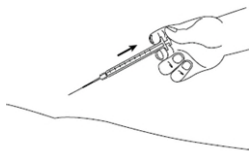
9. Gently pinch the skin at the injection site and holding the needle at an angle advised by your doctor or nurse, insert it into the skin.



10. Keeping your skin pinched, slowly press down the plunger as far as it will go until all the solution is injected. Hold this position for 5 seconds.



11. Slowly release the skin and gently pull the needle out.



IMPORTANT: If you injected yourself, put the cover back on the needle. If a carer has carried out the injection, they should not recap the needle in case of needle-stick injury.

12. Dispose of every used syringe and needle immediately in a standard approved sharps container. Any unused medicine or waste material should be disposed of in a manner that meets local requirements. Your doctor or nurse can provide disposal information as well as your local council.

Seek advice if you plan to travel.

When to inject it

Take SIGNIFOR® twice a day (approximately every 12 hours).

Using SIGNIFOR® at the same time each day will help you remember when to use your medicine.

How long to inject it

Do not stop taking SIGNIFOR® unless your doctor tells you to.

This medicine helps to control your condition, but does not cure it. If you interrupt your treatment with SIGNIFOR® your cortisol level may increase again and your symptoms may come back. Therefore, you should not stop using SIGNIFOR® without discussing it with your doctor.

If you forget to inject it

If you forget to administer a dose of SIGNIFOR® simply take your next injection at the scheduled time.

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

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

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

If you inject too much SIGNIFOR®

If you think that you have used too much SIGNIFOR®, 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.

5. What should I know while using SIGNIFOR®?

Things you should do

If you experience extreme weakness, weight loss, nausea, vomiting and low blood pressure seek urgent medical attention.

These are some of the signs and symptoms associated with a lack of cortisol.

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

Your doctor may wish to monitor the following:

- your blood glucose levels

You may need to start taking or adjust your anti-diabetic medication.

- 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 driving, operating machinery or doing jobs that require you to be alert until you know how SIGNIFOR® affects you.

Looking after your medicine

Keep this medicine in the original package in order to protect it from light.

Store it in a cool, dry place below 30°C.

Do not leave it in the car or on window sills.

Keep this 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

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.

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.

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® 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal System</p> <ul style="list-style-type: none"> • Diarrhoea • Abdominal pain • Abdominal expansion • Bloating • Nausea • Vomiting • Constipation • Oily or fatty stools • Discoloured stools • Loss of appetite <p>Hematological System</p> <ul style="list-style-type: none"> • Low blood pressure (hypotension) <p>Endocrine System</p> <ul style="list-style-type: none"> • Change in glucose levels in blood <p>Skin and Hair</p> <ul style="list-style-type: none"> • Hair loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>Musculoskeletal System</p> <ul style="list-style-type: none"> • Joint pain • Back pain • Pain in the extremities • Muscle pain <p>Respiratory System</p> <ul style="list-style-type: none"> • Common cold <p>Nervous System</p> <ul style="list-style-type: none"> • Headache • Dizziness • Vertigo • Fatigue or weakness <p>General/Systemic</p> <ul style="list-style-type: none"> • Pain, discomfort, itching and swelling at the injection site • Flu like symptoms • Dry skin or itchiness • Insomnia • Anxiety • Swelling due to fluid retention 	
--	--

Serious side effects

Serious side effects	What to do
<p>Endocrine System</p> <ul style="list-style-type: none"> • 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 • Low cortisol levels (you may experience extreme weakness, weight loss, nausea, vomiting, low blood pressure) <p>Cardiovascular System</p> <ul style="list-style-type: none"> • Slow heart rate • Irregular heart rate <p>Gastrointestinal System</p> <ul style="list-style-type: none"> • Gallstones (you may experience sudden back pain or pain on the right side of your abdomen) • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> Inflammation of gallbladder with signs of upper abdominal pain (cholecystitis) 	
--	--

The above list includes serious side effects which require immediate medical attention.

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 of these side effects, for example, anaemia, changes in liver function, pancreatic function, blood coagulation parameters and abnormal blood test results (sign of high level of fat in the blood) 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. 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.

7. Product details

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

What SIGNIFOR® contains

Active ingredient (main ingredient)	pasireotide Each ampoule contains 300 micrograms (mcg) or 600 micrograms (mcg) or 900 micrograms (mcg) pasireotide.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> mannitol tartaric acid sodium hydroxide water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What SIGNIFOR® looks like

SIGNIFOR® is supplied as a solution for injection in a 1 mL one point-cut colourless glass ampoule.

SIGNIFOR® comes in packs of 6, 30 or 60 ampoules.

Not all pack sizes are marketed.

Australian Registration Numbers:

SIGNIFOR® 300 mcg AUST R 201485

SIGNIFOR® 600 mcg AUST R 201484

SIGNIFOR® 900 mcg AUST R 201486

Who distributes SIGNIFOR®

Australia

Recordati Rare Diseases Australia Pty Ltd

Level 10

100 Arthur Street

North Sydney

NSW 2060

Australia

Phone: +61 (0) 408 061 403

rrdaustraliainfo@recordati.com

New Zealand

Pharmacy Retailing (NZ) Ltd/ Health Care Logistics

P O Box 62027

Sylvia Park

AUCKLAND 1644

Telephone: +64 9 918 5100

This leaflet was prepared in January 2026.

® = Registered Trademark