REMODULIN™

Treprostinil sodium

Consumer Medicine Information

What is this leaflet for

This leaflet answers some common questions about REMODULIN Injection. It does not contain all of the available information. Reading this leaflet 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 being given REMODULIN Injection against the benefits they expect it will have for you.

If you have any concerns about being given REMODULIN Injection, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What REMODULIN Injection is given for

REMODULIN Injection contains a medicine called treprostinil sodium which acts directly upon the blood vessels supplying the lungs and the body and causes the vessels to widen. It also stops platelets (blood cells which help blood to clot) from getting together.

In a disease such as Pulmonary Arterial Hypertension (PAH), the blood pressure in the lungs is higher than normal. The increased blood pressure in the lungs places a strain on the heart. This strain causes the heart to pump less blood into the lungs, causing shortness of breath, tiredness, and, as heart failure develops swelling in the feet and abdomen.

REMODULIN Injection helps improve symptoms associated with exercise in patients with pulmonary arterial hypertension.

Your doctor may have prescribed REMODULIN Injection for another use. Ask your doctor if you have any questions about why it has been prescribed for you.

REMODULIN is intended for use as a multidose (more than one dose) vial in individual patients only.

REMODULIN is for subcutaneous (under the skin) use only.

REMODULIN is not recommended for children under 16 years old. The safety and effectiveness in children has not been established.

REMODULIN Injection is not addictive.

REMODULIN Injection is only available on a doctor's prescription.

Before you are given REMODULIN Injection

When you must not be given it

You must not be given REMODULIN Injection if:

- You are allergic to treprostinil or to structurally related medicines, or any of the ingredients listed at the end of this leaflet.

Signs of allergic reactions may include itchy skin rash, shortness of breath and swelling of the face or tongue.

- If you become pregnant whilst you are given REMODULIN Injection, you should see your doctor immediately.

Young women being given REMODULIN Injection and who are at risk of becoming pregnant should make sure that they are using adequate contraception.

- If the expiry date printed on the vial or carton has passed.
- If the packaging is torn, product is deteriorated or the infusion pump is broken

Before you are given it

Tell your doctor if:

1. **You have any allergies.**
2. **You are pregnant or intend to become pregnant or are breastfeeding or wish to breastfeed.**

Your doctor will discuss the risks and benefits of being given REMODULIN Injection if you are pregnant or breastfeeding.

3. **You have Kidney or liver disease**
4. **You have a bleeding or clotting disorder**
5. **You have a heart abnormality (eg. shunt)**
6. **You are taking or have taken epoprostenol**

REMODULIN may cause pain or a reaction at the injection site.

If you have not told your doctor about any of the above, tell him/her before you are given REMODULIN.

Taking other medicines

Tell your doctor 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 may interfere with the action of REMODULIN. These include:

- Diuretics, a medicine used to increase the volume of urine
- Antihypertensive agents, a medicine used to help lower high blood pressure
- Vasodilators, a medicine used to widen blood vessels
- Antiplatelet agents, a medicine used to prevent blood clots
- Anticoagulants, a medicine used to prevent blood clots

These medicines may be affected by REMODULIN, or may affect how well it works. You may need to be given different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor has more information on medicines to be careful with or avoid while being given REMODULIN.

How REMODULIN is given

Treatment with REMODULIN Injection will be started in a hospital under the supervision of your doctor or nurse. While in hospital, your doctor or nurse will show you how your medicine is given and give you detailed instructions for the use and adjustment of your pump.

REMODULIN is infused (given by slow Injection) continuously through a self-inserted subcutaneous (under the skin) catheter, using a small portable pump that is fixed in place under your clothes. Therapy with REMODULIN will be needed for prolonged periods, possibly years.

Since REMODULIN will be needed for a long time, you should ensure that you are able to place and care for the subcutaneous catheter and to use the pump as shown. You should change the subcutaneous catheter every 3 days.

REMODULIN Injection is supplied in a multi-use (containing more than one dose) vial. Therefore, to stop dirt and microorganisms (germs) from entering the vial due to repeated entries, wipe the top of the vial clean with an alcohol swab before and after each piercing of the stopper with a needle. If microorganisms (germs) are injected into your body, they can cause infection at the injection site or in your body.

This product should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. If either particulate matter or discolouration is noted, REMODULIN should not be administered.

How much is given

The amount of REMODULIN given depends on the signs and symptoms of your disease and will be determined by your doctor. Your doctor may increase or decrease the dose, depending on how you respond.

Your dose may need to be adjusted if you are elderly, overweight or have kidney or liver disease.

You should not at any time stop the infusion of REMODULIN Injection unless your doctor tells you to. Sudden interruption or withdrawal of REMODULIN may result in worsening of PAH symptoms.

If you feel unwell during your course of treatment, contact your doctor.

If you forget to take it

If you forget to take your REMODULIN telephone your doctor for advice. Do not take twice as much to make up for the dose you missed.

If you take too much (overdose)

If you take too much REMODULIN telephone your doctor or go to casualty at your nearest hospital immediately.

Signs and symptoms of taking too much REMODULIN include flushing, headache, nausea, vomiting, diarrhoea and fainting.

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While you are being given REMODULIN Injection

Things you must do

Make sure that all of your doctors and pharmacists know that you are being given REMODULIN Injection. Remind them if any new medicines are about to be started.

You should ensure that you are able to place and care for the subcutaneous catheter and to use an infusion pump as you have been instructed.

Each time you draw up a dose of REMODULIN you should wipe the top of the vial clean with an alcohol swab before and after each piercing of the stopper with the needle.

You should change the subcutaneous catheter every 3 days.

Things that you must not do

Do not give REMODULIN to anyone else, even if they have the same conditions as you.

Do not at any time stop or reduce the amount of REMODULIN Injection you are taking until you speak with your doctor.

Do not run out of REMODULIN. REMODULIN therapy should not be interrupted. You should ensure you have enough medicine to take as directed by your doctor at all times.

Side Effects

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

- Skin irritation (redness) at the site of the infusion
- Infusion site bleeding, bruising or formation of abscess
- Site pain
- headache
- Diarrhoea
- Pruritus (itching)
- Raised red skin rash or infection
- Nausea (feeling sick)
- Jaw pain
- Bone pain
- Rash
- Oedema (swelling)
- Dizziness
- Loss of appetite

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice worsening of any of the following symptoms:

- Flushing, headache, dizziness, vomiting, diarrhoea, bleeding (eg. nose, bowel) and abnormal heart rhythm.
- Redness, tenderness, pain or swelling which may be an indication of a blood clot.

Other side effects not listed above may also occur in some patients. Problems with the drug delivery system may also lead to side effects. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

REMODULIN may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how REMODULIN affects you.

After using REMODULIN Injection

Storage

- Keep vials of REMODULIN Injection in a cool dry place where the temperature stays below 25°C.
- Once pierced, a vial of REMODULIN Injection is acceptable for repeated entry for no more than 30 days from the date of first entry, when stored below 25°C.
- During use, a single reservoir (syringe) of REMODULIN Injection can be administered up to 72 hours at 37°C.
- Do not store vials or any other medicine in the bathroom or near a sink.
- Do not leave vials in the car on hot or cold days. Heat, cold and dampness can destroy some medicines.
- Keep vials of REMODULIN Injection where children cannot reach them. A locked cupboard at least one- and-a-half metres above the ground is a good place to store medicines.
- Dispose of the needles as instructed in the containers provided by your nurse.

Disposal

Return any unused medicine to your pharmacist.

Product description

What REMODULIN Injection looks like

REMODULIN Injection is supplied in 20 mL multi-use vials at concentrations of 1.0 mg/mL, 2.5 mg/mL, 5.0 mg/mL and 10.0 mg/mL treprostinil, as a clear, colourless to slightly yellow solution, essentially free from visible particulate matter, individually packaged in a carton.

Ingredients

Each mL contains treprostinil sodium equivalent to 1.0mg/mL, 2.5 mg/mL, 5.0 mg/mL or 10.0 mg/mL treprostinil.

REMODULIN Injection also contains the following inactive ingredients:

Metacresol
Sodium hydroxide
Sodium chloride
Water for Injection

Manufacturer/Supplier

REMODULIN Injection is manufactured in the USA by
Baxter Pharmaceutical Solutions LLC
Bloomington, IN 47403

and is supplied in Australia by:
Orphan Australia Pty. Ltd.
48 Kangan Drive
Berwick
Victoria 3806.
Telephone (03) 9769 5744
Email info@orphan.com.au
Website www.orphan.com.au

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REMODULIN Injection 1.0 mg/mL
AUST R 101646
REMODULIN Injection 2.5 mg/mL
AUST R 101647
REMODULIN Injection 5.0 mg/mL
AUST R 101648
REMODULIN Injection 10.0 mg/mL
AUST R 101649

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