Package leaflet: Information for the user

Treprostinil Reddy 1 mg/ml, oplossing voor infusie
Treprostinil Reddy 2,5 mg/ml, oplossing voor infusie
Treprostinil Reddy 5 mg/ml, oplossing voor infusie
Treprostinil Reddy 10 mg/ml, oplossing voor infusie

treprostinil

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What [Invented Name] is and what it is used for

What [Invented Name] is
The active ingredient of [Invented Name] is treprostinil.
Treprostinil belongs to a group of medicines which work in a similar way to the naturally occurring prostacyclins. Prostacyclins are hormone-like substances which reduce blood pressure by relaxing blood vessels, causing them to widen, which allows the blood to flow more easily. Prostacyclins can also have an influence in preventing blood from clotting.

What [Invented Name] is used to treat
[Invented Name] is used to treat idiopathic or heritable pulmonary arterial hypertension (PAH) in patients with moderate severity of the symptoms. Pulmonary arterial hypertension is a condition where your blood pressure is too high in the blood vessels between the heart and the lungs, causing shortness of breath, dizziness, tiredness, fainting, palpitations or abnormal heartbeat, dry cough, chest pain and swollen ankles or legs.

[Invented Name] is initially administered as a continuous subcutaneous (under the skin) infusion. Some patients may become unable to tolerate this because of local site pain and swelling. Your doctor will decide whether [Invented Name] can be administered by continuous intravenous (directly into a vein) infusion instead. This will require the insertion of a central venous tube (catheter) that is usually located in your neck, chest or groin.

How [Invented Name] works
[Invented Name] lowers blood pressure within the pulmonary artery, by improving blood flow and reducing the amount of work for the heart. Improved blood flow leads to an improved supply of oxygen to the body and reduced strain on the heart, causing it to function more effectively. [Invented Name] improves the symptoms associated with PAH and the ability to exercise in patients who are limited in terms of activity.

2. What you need to know before you use [Invented Name]

Do not use [Invented Name]
- if you are allergic (hypersensitive) to treprostinil, metacresol or any of the other ingredients of this medicine listed in section 6
- if you have been diagnosed with a disease called "pulmonary veno-occlusive disease". This is a disease in which the blood vessels that carry blood through your lungs become swollen and clogged resulting in a higher pressure in the blood vessels between the heart and the lungs.
- if you have severe liver disease
- if you have a heart problem, for example:
    - a myocardial infarction (heart attack) within the last six months
    - severe changes in heart rate
    - severe coronary heart disease or unstable angina
    - a heart defect has been diagnosed, such as a faulty heart valve that causes the heart to work poorly
    - any disease of the heart which is not being treated or not under close medical observation
- if you are at a specific high risk of bleeding – for example, active stomach ulcers, injuries, or other bleeding conditions
- if you have had a stroke within the last 3 months, or any other interruption of blood supply to the brain.

Warnings and precautions
Before you start taking [Invented Name], tell your doctor:
- if you suffer from any liver disease
- if you have been advised that you are medically obese (BMI greater than 30 kg/m^2)
- if you have Human Immunodeficiency Virus (HIV) infection
- if you have high blood pressure in your liver veins (portal hypertension).
- if you have a birth defect in your heart which affects the way your blood flows through it.

During your treatment with [Invented Name], tell your doctor:
- if your blood pressure decreases (hypotension)
- if you experience a rapid increase in breathing difficulties or persistent cough (this can be related to congestion in the lungs or asthma or other condition), **consult your doctor immediately.**
- if you have excessive bleeding as treprostinil may increase the risk, by preventing your blood from clotting
- if you develop a fever whilst receiving intravenous [Invented Name] or the intravenous infusion site becomes red, swollen and / or painful to the touch, as this could be a sign of infection.

Other medicines and [Invented Name]
Please tell your doctor if you are taking or have recently taken, or might use any other medicines.

Please tell your doctor if you are taking:
- medicines used to treat **high blood pressure** (antihypertensive drugs or other vasodilators)
- drugs used to increase the rate of **urination** (diuretics) including furosemide
- medicines that stop **blood clotting** (anticoagulants) such as warfarin, heparin or nitric oxide based products
- any non-steroidal anti-inflammatory (**NSAID**) drugs (e.g. acetylsalicylic acid, ibuprofen)
- medicines that may increase or decrease the effect of [Invented Name] (e.g. gemfibrozil, rifampicin, trimethoprim, deferasirox, phenytoin, carbamazepine, phenobarbital, St John's Wort) as your doctor may need to adjust your dose of [Invented Name].

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

[Invented Name] is not recommended if you are pregnant, planning to become pregnant, or think that you might be pregnant, unless considered essential by your doctor. The safety of this medicine for use during pregnancy has not been established.

[Invented Name] is not recommended for use in breast-feeding, unless considered essential by your doctor. You are advised to stop breast-feeding if [Invented Name] is prescribed for you, because it is not known whether this medicine passes into breast milk.

Women of child-bearing potential
Contraception is strongly recommended during [Invented Name] treatment.

Driving and using machines
[Invented Name] may induce low blood pressure with dizziness or fainting. In such a case do not drive or operate machinery and ask your doctor for advice.

[Invented Name] contains sodium and metacresol
This medicine contains 74.0 mg (1mg/ml), 74.9 mg (2.5 mg/ml), 78.4 mg (5mg/ml) and 74.8 mg (10mg/ml) sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.7 % (1 mg/ml, 2.5 mg/ml and 10 mg/ml) and 3.9 % (5 mg/ml) of the recommended maximum daily dietary intake of sodium for an adult.

Metacresol may cause allergic reactions.

3. How to use [Invented Name]

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

[Invented Name] is administered as a continuous infusion, either:

- Subcutaneously (under the skin) via a small tube (cannula) which is located in your abdomen or thigh; or,
- Intravenously via a tube (catheter) that is usually located in your neck, chest or groin.

For subcutaneous infusion the product should be administered undiluted.
For intravenous infusion the product should be diluted in accordance with the instructions of the prescriber and may only be diluted with sterile water for injection or 0.9% (w/v) of sodium chloride injection.

In both cases, [Invented Name] is pushed through the tubing by a portable pump

Before you leave the hospital or clinic, the doctor will tell you how to prepare [Invented Name] and at what rate the pump should deliver your [Invented Name]. Information on how to use the pump correctly and what to do if it stops working should also be given to you. The information should also tell you who to contact in an emergency.
Flushing of the infusion line whilst connected may cause accidental overdose.

[Invented Name] is diluted only when administered with a continuous intravenous infusion:

For intravenous infusion only: You must only dilute your [Invented Name] solution with either Sterile Water for Injection or 0.9% Sodium Chloride Injection (as provided by your doctor) if it is being administered as a continuous intravenous infusion.

Adult patients
[Invented Name] is available as 1 mg/ml, 2.5 mg/ml, 5 mg/ml or 10 mg/ml solution for infusion. Your doctor will determine the infusion rate and dose appropriate for your condition.

Overweight patients
If you are overweight (weigh 30% or more than your ideal body weight) your doctor will determine the initial and subsequent doses based on your ideal body weight. Please also refer to Section 2, “Warnings and precautions”.

Older people
Your doctor will determine the infusion rate and dose appropriate for your condition.

Children and adolescents
Limited data are available for children and adolescents.

Dosage adjustment
The infusion rate can be reduced or increased on an individual basis under **medical supervision only**.

The aim of adjusting the infusion rate is to establish an effective maintenance rate which improves symptoms of PAH while minimizing any undesirable effects.

If your symptoms increase or if you need complete rest, or are confined to your bed or chair, or if any physical activity brings on discomfort and your symptoms occur at rest, do not increase your dose without medical advice. [Invented Name] may no longer be sufficient to treat your disease and another treatment may be required.

How can blood stream infections during treatment with intravenous [Invented Name] be prevented?
As with any long-term intravenous treatment, there is a risk of getting blood stream infections. Your doctor will train you on how to avoid this.

If you use more [Invented Name] than you should
If you accidentally overdose on [Invented Name], you may experience nausea, vomiting, diarrhoea, low blood pressure (dizziness, light-headedness or fainting), skin flushes and/or headaches.

If any of these effects become severe then you should contact your doctor or hospital immediately. Your doctor may reduce or discontinue the infusion until your symptoms have disappeared. [Invented Name] solution for infusion will then be reintroduced at a dose level recommended by your doctor.

If you stop using [Invented Name]
Always use [Invented Name] as directed by your doctor or hospital specialist. Do not stop using [Invented Name] unless your doctor has advised you to.

Abrupt withdrawal or sudden reductions in the dose of [Invented Name] may cause the pulmonary arterial hypertension to return with the potential for rapid and severe deterioration in your condition.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)
- widening of blood vessels with flushing of the skin.
- pain or tenderness around the infusion site
- skin discolouration or bruising around the infusion site
- headaches
- skin rashes
- nausea
- diarrhoea
- jaw pain

Common side effects (may affect up to 1 in 10 people)
- dizziness
- vomiting
- light-headedness or fainting due to low blood pressure
- itching or redness of the skin

- swelling of feet, ankles, legs or fluid retention
- bleeding episodes such as nose bleeds, coughing up blood, blood in the urine, bleeding from the gums, blood in the faeces
- joint pain, muscle pain, pain in the legs and/or arms

Other possible side effects (frequency not known (cannot be estimated from the available data))
- infection at the infusion site
- abscess at the infusion site
- a decrease of blood clotting cells (platelets) in the blood (thrombocytopenia)
- bleeding at the infusion site
- bone pain
- skin rashes with discolouration or raised bumps
- tissue infection under the skin (cellulitis)
- Too much pumping of blood from the heart leading to shortness of breath, fatigue, swelling of the legs and abdomen due to fluid build-up, persistent cough

Additional side effects associated with the intravenous route of administration
- inflammation of the vein (thrombophlebitis)
- blood stream bacterial infection (bacteraemia)* (refer to Section 3)
- septicaemia (severe blood bacterial infection)

* life-threatening or fatal cases of blood stream bacterial infection have been reported

Reporting of side effects
If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented Name]

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

During continuous subcutaneous infusion, a single reservoir (syringe) of undiluted [Invented Name] must be used within 72 hours.

During continuous intravenous infusion, a single reservoir (syringe) of diluted [Invented Name] must be used within 24 hours.
A [Invented Name] vial must be used or discarded within 30 days after first opening. Any remaining diluted solution should be discarded.

Do not use this medicine after the expiry date which is stated on the carton and vial after "EXP". The expiry date refers to the last day of that month.
Do not use this medicine if you notice any damage to the vial, discolouration or other signs of deterioration (e.g. presence of particles)..

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented Name] contains
The active substance is treprostinil. Each ml contains 1 mg, 2.5 mg, 5 mg, 10 mg treprostinil (as treprostinil sodium). Each vial of 20 ml contains 20 mg, 50 mg, 100 mg, 200 mg treprostinil (as treprostinil sodium).
The other ingredients are:
Sodium citrate (E331), sodium chloride, metacresol, water for injections and for pH adjustment, sodium hydroxide (E524) and hydrochloric acid (E507).

What [Invented Name] looks like and contents of the pack

[Invented Name] is a clear colourless to slightly yellow solution, available in a glass vial with rubber stopper sealed with a (specified colour) flip-off plastic cap with aluminium seal:

- [Invented Name] 1 mg/ml solution for infusion has a yellow cap.
- [Invented Name], 2.5 mg/ml solution for infusion has a blue cap.
- [Invented Name], 5 mg/ml solution for infusion has a green cap.
- [Invented Name], 10 mg/ml solution for infusion has a red cap.

Each carton contains one vial of 20 ml solution for infusion.

Marketing Authorisation holder:

Vergunninghouder:
Reddy Holding GmbH
Kobelweg 95
86156 Augsburg
Duitsland

Fabrikant:
betapharm Arzneimittel GmbH
Kobelweg 95
86156 Augsburg
Duitsland

In het register ingeschreven onder:

Treprostinil Reddy 1 mg/ml, oplossing voor infusie - RVG 127411
Treprostinil Reddy 2,5 mg/ml, oplossing voor infusie - RVG 127412
Treprostinil Reddy 5 mg/ml, oplossing voor infusie - RVG 127413
Treprostinil Reddy 10 mg/ml, oplossing voor infusie - RVG 127414

This medicine is authorised in the Member States of the European Economic Area under the following names:

België:	Treprostinil Reddy 1 mg/ml oplossing voor infusie Treprostinil Reddy 2,5 mg/ml oplossing voor infusie Treprostinil Reddy 5 mg/ml oplossing voor infusie Treprostinil Reddy 10 mg/ml oplossing voor infusie
Tsjechië:	Treprostenil Reddy 1 mg/ml infuzní roztok Treprostenil Reddy 2,5 mg/ml infuzní roztok Treprostenil Reddy 5 mg/ml infuzní roztok Treprostenil Reddy 10 mg/ml infuzní roztok

Denemarken:	Treprostinil Reddy 1 mg/ml infusionvæske, opløsning Treprostinil Reddy 2,5 mg/ml infusionvæske, opløsning Treprostinil Reddy 5 mg/ml infusionvæske, opløsning Treprostinil Reddy 10 mg/ml infusionvæske, opløsning
Duitsland:	Treprostenil beta 1 mg/ml Infusionslösung Treprostenil beta 2,5 mg/ml Infusionslösung Treprostenil beta 5 mg/ml Infusionslösung Treprostenil beta 10 mg/ml Infusionslösung
Finland:	Treprostenil Reddy 1 mg/ml infuusioneste, liuos Treprostenil Reddy 2,5 mg/ml infuusioneste, liuos Treprostenil Reddy 5 mg/ml infuusioneste, liuos Treprostenil Reddy 10 mg/ml infuusioneste, liuos
Hongarije:	Treprostinil Reddy 1 mg/ml oldatos infúzió Treprostinil Reddy 2,5 mg/ml oldatos infúzió Treprostinil Reddy 5 mg/ml oldatos infúzió Treprostinil Reddy 10 mg/ml oldatos infúzió
Ierland:	Treprostenil Reddy 1 mg/ml solution for infusion Treprostenil Reddy 2.5 mg/ml solution for infusion Treprostenil Reddy 5 mg/ml solution for infusion Treprostenil Reddy 10 mg/ml solution for infusion
Nederland:	Treprostinil Reddy 1 mg/ml oplossing voor infusie Treprostinil Reddy 2,5 mg/ml oplossing voor infusie Treprostinil Reddy 5 mg/ml oplossing voor infusie Treprostinil Reddy 10 mg/ml oplossing voor infusie
Noorwegen:	Treprostinil Reddy 1 mg/ml infusjonsvæske, oppløsning Treprostinil Reddy 2,5 mg/ml infusjonsvæske, oppløsning Treprostinil Reddy 5 mg/ml infusjonsvæske, oppløsning Treprostinil Reddy 10 mg/ml infusjonsvæske, oppløsning
Polen:	Treprostinil Reddy 1 mg/ml roztwór do infuzji Treprostinil Reddy 2,5 mg/ml roztwór do infuzji Treprostinil Reddy 5 mg/ml roztwór do infuzji Treprostinil Reddy 10 mg/ml roztwór do infuzji
Portugal:	Treprostinil Reddy 1 mg/ml solução para perfusão Treprostinil Reddy 2,5 mg/ml solução para perfusão Treprostinil Reddy 5 mg/ml solução para perfusão Treprostinil Reddy 10 mg/ml solução para perfusão

Slowakije:	Treprostinil Reddy 1 mg/ml infúzny roztok Treprostinil Reddy 2,5 mg/ml infúzny roztok Treprostinil Reddy 5 mg/ml infúzny roztok Treprostinil Reddy 10 mg/ml infúzny roztokg
Zweden:	Treprostinil Reddy 1 mg/ml infusionsvätska, lösning Treprostinil Reddy 2,5 mg/ml infusionsvätska, lösning Treprostinil Reddy 5 mg/ml infusionsvätska, lösning Treprostinil Reddy 10 mg/ml infusionsvätska, lösning

Deze bijsluiter is voor het laatst goedgekeurd in april 2022