Epoprostenol MYX™ for Injection

epoprostenol sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EPOPROSTENOL MYX. 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 using EPOPROSTENOL MYX against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine.
You may need to read it again.

What EPOPROSTENOL MYX is used for

Epoprostenol is used to treat some types of pulmonary arterial hypertension (PAH). PAH is characterised by high blood pressure in the blood vessel that carries blood from the heart to the lungs, and increased resistance in the blood vessels of the lung. The cause of PAH is not known however there are a number of diseases such as scleroderma that are associated with PAH. Epoprostenol belongs to a group of medicines called prostaglandins.

Epoprostenol works by widening the blood vessels in the lungs and so lowering the blood pressure in your lungs (known as a vasodilator action).

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.

Epoprostenol is not addictive.

Before you use EPOPROSTENOL MYX

When you must not use it

- **Do not use Epoprostenol if you have ever had an allergic reaction to epoprostenol or any of the ingredients listed at the end of this leaflet.**
  Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.
- **Do not use Epoprostenol if you have heart disease with shortness of breath, and swelling of the feet or legs due to fluid build-up.**
- **Do not use Epoprostenol after the expiry date printed on the pack.**
  If you use it after the expiry date has passed, it may not work as well.
- **Do not use Epoprostenol if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you are pregnant, trying to become pregnant, or breastfeeding.**
- **you are taking any medicine to prevent blood clots, such as heparin, warfarin, aspirin or other anti-inflammatory pain killers (NSAIDs).**
- **you are taking any medicines that are used to treat high blood pressure, or a group of medicines known as nitrates that are used to treat angina.**
- **you are taking digoxin, a medicine used to treat heart failure.**
- **you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using EPOPROSTENOL MYX with other medicines.

How to use EPOPROSTENOL MYX

EPOPROSTENOL MYX will be given as an intravenous infusion only, normally through a permanently fitted intravenous catheter (during initial treatment a 'peripheral line' may be used which is a non-permanent catheter). Before EPOPROSTENOL MYX is used, it must be dissolved only in the specific DILUENT supplied with EPOPROSTENOL MYX.

How much to use

Initial treatment with EPOPROSTENOL MYX will be carried out in a hospital. Your doctor will start you on an infusion and slowly increase the dose (every 15 minutes) to find the most effective or largest dose you can tolerate. During this part of the treatment you will also learn about how your body reacts to EPOPROSTENOL MYX.

Your doctor will then continue the infusion based on this dose, and may increase or decrease your infusion rate depending on your response to the treatment. All changes should be done gradually and under the direction of a doctor, except in emergency situations.

If you develop pulmonary oedema (water on the lungs) during this time, your doctor may choose not to treat you with EPOPROSTENOL MYX.

How to use it

Your EPOPROSTENOL MYX infusion will be given to you as continuous intravenous infusion only, normally through a permanently fitted intravenous catheter through a pump. There are only certain pumps which can be used. Your doctor will make sure you are using the right one.

Your doctor or nurse will have shown you how to keep your catheter clean, and the area around it clean and free from infection. They will also show you how to prepare and administer e and how to stop treatment if necessary. It is very important you follow their instructions carefully.

The DILUENT contains no preservative. Use a vial once only and then discard.

How long to use it

Use EPOPROSTENOL MYX for as long as your doctor advises you to.

EPOPROSTENOL MYX is generally used over a prolonged period of time, possibly years. It should not be stopped suddenly. Symptoms of suddenly stopping EPOPROSTENOL MYX include dizziness, weakness and difficulty breathing.

If you use too much (overdose)

As EPOPROSTENOL MYX has vasodilatory action, overdose may lead to low blood pressure, loss of consciousness, nausea, diarrhoea, vomiting, facial flushing, headache and fast heart beat.

In hospital, the effects of EPOPROSTENOL MYX are monitored carefully by your doctor. In the unlikely event that you receive too much, appropriate action, such as reducing the dose can be taken promptly.

If you are using EPOPROSTENOL MYX at home and you think you have used too much, immediately telephone your doctor or the nearest hospital casualty department, even if there are no signs of discomfort. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are using EPOPROSTENOL MYX

Things you must do

Tell your doctor or pharmacist that you are using EPOPROSTENOL MYX if you are about to start on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.
Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop using or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use EPOPROSTENOL MYX to treat any other complaints unless your doctor says to.

Things to be careful of

As with many other medicines, EPOPROSTENOL MYX may cause dizziness/ drowsiness/tiredness in some people.

Be careful driving or operating machinery until you know how EPOPROSTENOL MYX affects you. If you are affected, do not drive or operate machinery.

Side Effects

Check with your doctor as soon as possible if you have any problems while taking EPOPROSTENOL MYX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, EPOPROSTENOL MYX can cause side effects in some people.

If you think you are having an allergic reaction to EPOPROSTENOL MYX while you are receiving it, TELL YOUR DOCTOR IMMEDIATELY. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

Tell your doctor at once if you experience any of the following while you are receiving EPOPROSTENOL MYX:

- fever
- fatigue
- chills/flu-like symptoms
- facial flushing or paleness
- fast heart beat
- shortness of breath
- diarrhoea
- feeling or being sick
- wind or tummy discomfort
- anxiety, nervousness and agitation
- dizziness, especially on standing
- headaches
- dry mouth
- rash
- decreased or increased feeling or sensitivity, especially in the skin
- tingling or numbness of the hands or feet
- chest pain and tightness
- reddening and pain at the infusion site
- sweating
- jaw, muscle and/or back pain
- bleeding: any bleeding can be serious, if this occurs you should contact your doctor

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

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor if you don't understand anything in this list.

EPOPROSTENOL MYX may affect your blood sugar levels, heart rate or blood pressure during infusion. Your doctor will monitor these.

It is very important to keep the area around the intravenous catheter clean, otherwise infection of the skin at the site of injection may result, which can then spread into your blood (known as septicaemia).

During administration of EPOPROSTENOL MYX the intravenous catheter may become blocked. Tell your doctor or pharmacist if this happens.

Storing EPOPROSTENOL MYX

Storage

Keep this medicine where young children cannot reach it.
A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Keep EPOPROSTENOL MYX powder and DILUENT in a cool, dry place where it stays below 25°C. Protect from light by keeping them in their cartons until use.

Do not store EPOPROSTENOL MYX powder or DILUENT in a bathroom or near a sink.

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

Do not freeze EPOPROSTENOL MYX powder and DILUENT at any time.

Once EPOPROSTENOL MYX powder has been dissolved with the diluent, if any of this infusion solution is not used, it should be used as soon as practicable. If storage is necessary, keep at 2°C - 8°C for not more than 24 hours.

If you have a 'cold pouch' with your infusion pump, then EPOPROSTENOL MYX may be used over a 24 hour period as long as the cold pouch is changed as necessary throughout the day. Only use a cold pouch which can keep the temperature of EPOPROSTENOL MYX below 15°C.

Do not freeze EPOPROSTENOL MYX at any time.

Product Description

What it looks like

EPOPROSTENOL MYX is a sterile white powder supplied with DILUENT in the following pack presentations:

- 0.5 mg (equivalent to 500 µg) vial of epoprostenol with 2 vials of DILUENT and a filter
- 1.5 mg vial of epoprostenol with 2 vials of DILUENT and a filter

Ingredients

EPOPROSTENOL MYX contains the active ingredient epoprostenol, as the sodium salt. It also contains glycine, sodium chloride, mannitol and sodium hydroxide.

The DILUENT for EPOPROSTENOL MYX contains glycine, sodium chloride, sodium hydroxide and Water for Injections.

Sponsor

Mayne Pharma International Pty Ltd
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Australian Registration Numbers:

EPOPROSTENOL MYX 500 µg with 2 vials of diluent: AUST R 211157

EPOPROSTENOL MYX 1.5 mg with 2 vials of diluent: AUST R 211158

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