

FLOLAN for INJECTION

EPOPROSTENOL SODIUM

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about FLOLAN. It does not contain all of 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 FLOLAN 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 the medicine.

You may need to read it again.

What FLOLAN is used for

FLOLAN 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. FLOLAN belongs to a group of medicines called prostaglandins.

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

Your doctor may have prescribed FLOLAN for another reason.

Ask your doctor if you have any questions about why FLOLAN has been prescribed for you.

FLOLAN is not addictive.

Before you use FLOLAN

When you must not use it

- **Do not use FLOLAN 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
 - hayfever
 - lumpy rash ("hives") or fainting.
- **Do not use FLOLAN if you have heart disease with shortness of breath, and swelling of the feet or legs due to fluid build-up.**
 - **Do not use FLOLAN after the expiry date [EXP.] printed on the pack.**

If you use it after the expiry date has passed, it may not work as well.

- **Do not use FLOLAN if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using FLOLAN, 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 have heart disease.**
- **you are pregnant, trying to become pregnant, or breast-feeding.**

- **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.**
- **you are on a sodium-controlled diet.**

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

How to use FLOLAN

FLOLAN 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 FLOLAN is used, it must be dissolved only in the specific DILUENT supplied with FLOLAN and filtered as directed by your doctor.

How much to use

Initial treatment with FLOLAN 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 FLOLAN.

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 in the lungs) during this time, your doctor may choose not to treat you with FLOLAN.

How to use it

Your FLOLAN 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 FLOLAN 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 FLOLAN for as long as your doctor advises you to. FLOLAN is generally used over a prolonged period of time, possibly years. It should not be stopped suddenly. Symptoms of suddenly stopping FLOLAN include dizziness, weakness and difficulty breathing.

If you use too much (overdose)

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

In hospital, the effects of FLOLAN 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 FLOLAN 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.

You can also call the Poison Information Centre at 13 11 26 for advice.

Keep telephone numbers for these places handy.

While you are using FLOLAN

Things you must do

Tell your doctor or pharmacist that you are using FLOLAN 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 you are breastfeeding or plan to breast feed.

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 FLOLAN to treat any other complaints unless your doctor says to.

FLOLAN must only be administered using the equipment and materials provided by your doctor, nurse or pharmacist. These must not be substituted.

Things to be careful of

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

Be careful driving or operating machinery until you know how FLOLAN 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 whilst taking FLOLAN, even if you do not think the problems are related to the medicine or are not listed in this leaflet.

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

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

Very common side effects

These may affect more than 1 in 10 people:

- headache

- jaw pain
- pain
- being sick (vomiting)
- feeling sick (nausea)
- diarrhoea
- redness of the face (flushing).

Common side effects

These may affect up to 1 in 10 people:

- infection of the blood (septicaemia)
- heart beating faster
- slow heart beat
- low blood pressure
- bleeding at various sites and bruising more easily than normal, for example from the nose or gums
- stomach discomfort or pain
- chest pain
- joint pain
- feeling anxious, feeling nervous

- rash
- pain at the injection site.

Common side effects that may show up in blood tests:

- decrease in the number of blood platelets (cells that help the blood to clot). This may lead to bleeding or bruising more easily than normal.

Uncommon side effects

These may affect up to 1 in 100 people:

- build-up of fluid in the lung (pulmonary oedema). This may lead to breathlessness, which may be very severe and usually worsens on lying down
- sweating
- dry mouth.

Rare side effects

These may affect up to 1 in 1,000 people:

- infection at the injection site.

Very rare side effects

These may affect up to 1 in 10,000 people:

- enlarged or overactive spleen. This may cause pain or fullness in the left upper abdomen that may spread to the left shoulder, feeling full without eating or after eating

only a small amount, fatigue, frequent infections and/or easy bleeding

- swelling due to build-up of fluid around the stomach
- feeling of tightness around the chest
- feeling tired, weak
- feeling agitated
- pale skin
- redness at the injection site
- overactive thyroid gland. This may lead to sudden weight loss, rapid heartbeat, increased sensitivity to heat, difficulty sleeping, fatigue and/or brittle hair.
- too much pumping of blood from the heart. This may lead to persistent cough, shortness of breath, fatigue, swelling of the legs and abdomen due to fluid build-up (high output cardiac failure).

If you think you are having an allergic reaction to FLOLAN 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.

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.

FLOLAN 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 FLOLAN the intravenous catheter may become blocked. Tell your doctor or pharmacist if this happens.

Storing FLOLAN

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 FLOLAN 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 FLOLAN powder or DILUENT in a bathroom or near a sink.

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

Do not freeze FLOLAN powder and DILUENT at any time.

Once FLOLAN powder has been dissolved with the diluent, it can be administered immediately or stored for up to 8 days at 2°C to 8°C prior to administration.

Following this preparation or storage, the solution should be used:

- within 72 hours if stored at temperatures up to 25°C,
- within 48 hours if stored at temperatures up to 30°C,
- within 24 hours if stored at temperatures up to 35°C and

- within 12 hours if stored at temperatures up to 40°C.

Discard any unused solution after this time.

Do not freeze FLOLAN at any time.

Product description

What FLOLAN looks like

FLOLAN is a sterile white to off-white powder supplied with DILUENT in the following pack presentations:

- 0.5 mg 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

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

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

Manufacturer

FLOLAN is supplied by:

GlaxoSmithKline Australia Pty Ltd

Level 4

436 Johnston Street,

Abbotsford, Victoria, 3067

Australia.

Further Information

This leaflet was prepared on 14 June 2018

The information provided applies only to: FLOLAN for Injection.

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FLOLAN 0.5 mg with 2 vials of DILUENT: AUST R 80342

FLOLAN 1.5 mg with 2 vials of DILUENT: AUST R 80343

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