

FLOLAN

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 being given FLOLAN?

FLOLAN contains the active ingredient epoprostenol sodium. FLOLAN is used to treat some types of pulmonary arterial hypertension (PAH). PAH is characterised by high blood pressure in the blood vessels between the heart and lungs.

For more information, see Section [1. Why am I being given FLOLAN?](#) in the full CMI.

2. What should I know before I am given FLOLAN?

Do not use if you have ever had an allergic reaction to epoprostenol sodium or any of the ingredients listed at the end of the CMI or if you have heart disease with shortness of breath and swelling of the feet or legs due to fluid build-up.

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.

For more information, see Section [2. What should I know before I am given FLOLAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLOLAN 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 am I given FLOLAN?

- FLOLAN is given as an intravenous infusion into a vein.
- Before you are given FLOLAN it must be dissolved with the supplied diluent and filtered.
- Your doctor or nurse will show you how to make up FLOLAN and how to administer it if you are using FLOLAN at home.

More instructions can be found in Section [4. How am I given FLOLAN?](#) in the full CMI.

5. What should I know while using FLOLAN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using FLOLAN• Tell your doctor if you have not used FLOLAN as intended• Call your doctor if you become pregnant, intend to become pregnant or are breastfeeding
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose without first checking with your doctor• Do not use any other piece of equipment or material to administer FLOLAN besides what your doctor or pharmacist have given you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until

	<p>you know how FLOLAN affects you</p> <ul style="list-style-type: none"> ● FLOLAN may cause dizziness, drowsiness or tiredness in some people
Looking after your medicine	<ul style="list-style-type: none"> ● Store FLOLAN below 25°C in the box to protect it from light. ● Do not freeze. ● Once FLOLAN has been mixed with the diluent it should be used immediately or stored as per the conditions listed in section 5 of the full CMI.

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

6. Are there any side effects?

Side effects which have been reported include headache, jaw pain, pain, nausea and vomiting, diarrhoea, stomach discomfort or pain, redness of the face (flushing), joint pain, rash, pain or redness at the injection site, sweating, dry mouth, feeling tired or weak, feeling anxious, nervous or agitated, palling of the skin. If you experience an allergic reaction (symptoms include wheezing, difficulty in breathing, swelling of the lips/mouth/tongue, hay fever, lumpy rash (“hives”) and

fainting) go to the Emergency Department of your nearest hospital immediately.
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.

FLOLAN

Active ingredient(s): *epoprostenol sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLOLAN. **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 FLOLAN.**

Where to find information in this leaflet:

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

1. Why am I being given FLOLAN?

FLOLAN contains the active ingredient epoprostenol sodium. FLOLAN belongs to a group of medicines called prostaglandins.

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 works by widening the blood vessels in the lungs which lowers the blood pressure in your lungs (known as vasodilator action).

2. What should I know before I am given FLOLAN?

Warnings

Do not use FLOLAN if:

- you are allergic to epoprostenol sodium, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have heart disease with shortness of breath and swelling of the feet or legs due to fluid build-up.

Check with your doctor if you:

- have any other medical conditions
- have heart disease
- take any medicines for any other condition

- take any medicine to prevent blood clots such as heparin, warfarin, aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- take any medicines to treat high blood pressure
- take medicines known as nitrates that are used to treat angina
- take digoxin which is used to treat heart failure
- are on a sodium controlled diet

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with FLOLAN and affect how it works.

- medicines used to prevent blood clots such as heparin, warfarin, aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines to treat high blood pressure
- nitrates, medicines used to treat angina
- digoxin, a medicine used to treat heart failure

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FLOLAN.

4. How am I given FLOLAN?

How is FLOLAN given

- FLOLAN is given as an intravenous infusion, normally through a permanently fitted intravenous catheter (during initial treatment a peripheral line may be used which is a non-permanent 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 show you how to keep your catheter clean and the area around it clean and free from infection. They will show you how to prepare and administer FLOLAN and how to stop treatment if necessary. It is very important to follow these instructions carefully.
- Before FLOLAN is given it must be dissolved only in the specific diluent supplied with the medicine and then filtered.

- The diluent does not contain any preservative. Use the vial once and then discard it.
- Tell your doctor or nurse if your catheter becomes blocked during the infusion.

How much is given

- Initial treatment with FLOLAN will start in hospital.
- your doctor will start you on an infusion and slowly increase the dose (every 15 mins) to find the most effective or largest dose you can tolerate (you will also learn how your body tolerates FLOLAN).
- Infusions will then continue based on the dose you can tolerate.
- The infusion rate may be increased or decreased depending on your response to treatment. All changes should be done gradually and under the direction of your doctor.
- If you develop pulmonary oedema (water on the lungs) during this time your doctor may decide to stop treating you with FLOLAN.

How long to take FLOLAN

- Use FLOLAN for as long as your doctor tells you to.
- FLOLAN is generally used over a long period of time, possibly years.
- Do not stop using FLOLAN suddenly. If you do, you might experience dizziness, weakness and difficulty breathing.

If you forget to use FLOLAN

FLOLAN should be used regularly at the time that your doctor tells you.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much FLOLAN

If you think that you may have been given too much FLOLAN, you may need urgent medical attention.

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

If you are being given FLOLAN 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 you should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), 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 FLOLAN?

Things you should do

- tell your doctor if you have not used FLOLAN as it was prescribed for you, otherwise they may change your treatment unnecessarily

Call your doctor straight away if you:

- become pregnant, intend to become pregnant
- are breastfeeding or intend to start breastfeeding

Remind any doctor, nurse, dentist or pharmacist you visit that you are using FLOLAN.

Things you should not do

- do not stop using this medicine suddenly or change the dosage 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 this medicine to treat any other complaints unless your doctor tells you to.

- do not use any other piece of equipment or material to administer FLOLAN besides what your doctor or pharmacist have given you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FLOLAN affects you.

FLOLAN may cause dizziness, drowsiness or tiredness in some people.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly. Keep the medicine in the box until it is time to use it to protect it from light.

Store FLOLAN and the diluent in in a cool dry place (below 25°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills
- in the freezer

Keep it where young children cannot reach it.

Once FLOLAN has been prepared with the diluent

- Administer the medicine immediately

When to discard your medicine

If you do not administer FLOLAN straight away you can store it under the following conditions:

- up to 48 hours if stored at temperatures up to 25°C
- up to 36 hours if stored at temperatures up to 30°C
- up to 24 hours if stored at temperatures up to 35°C
- up to 12 hours if stored at temperatures up to 40°C
- up to 8 days if kept between 2°C and 8°C

Any unused solution should be discarded after the above times have passed.

Never freeze FLOLAN.

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.

6. Are there any side effects?

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● headache● jaw pain● pain● nausea and vomiting● diarrhoea● stomach discomfort or pain● redness of the face (flushing)● joint pain● rash● pain or redness at the injection site● sweating● dry mouth● feeling tired, weak● feeling anxious, nervous or agitated● palling of the skin● low blood pressure● heart beating faster● slow heart beat	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● allergic reaction, symptoms include wheezing, difficulty in breathing, swelling of the lips/mouth/tongue, hay fever, lumpy rash (“hives”) and fainting● too much blood being pumped from the heart which may lead to persistent cough, shortness of breath, fatigue, swelling of the legs and abdomen due to fluid build-up (high output cardiac failure)● bleeding at various sites and bruising more easily than normal, for example from the nose or gums● infection of the blood (septicaemia)● chest pain, feeling of tightness around the chest	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> ● a build-up of fluid in the lung (pulmonary oedema) which may lead to breathlessness, which may be very severe and usually worsens upon lying down ● swelling due to the build-up of fluid around the stomach ● infection at the injection site ● enlarged or overactive spleen which may cause pain or a feeling of 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 easily bleeding ● symptoms of an overactive thyroid gland which may lead to sudden weight loss, a rapid heartbeat, 	

Serious side effects	What to do
increased sensitivity to heat, difficulty sleeping, fatigue and/or brittle hair	

If you have a blood test it might show a decrease in the number of platelets (cells that help the blood clot). This may lead to bleeding or bruising more easily than normal.

FLOLAN may affect your blood sugar levels, heart rate and blood pressure during the infusion. Your doctor will monitor these.

It is important to keep the area around the catheter clean. If the skin around the catheter becomes infected it can potentially spread into your blood (known as septicaemia).

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.

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 FLOLAN contains

Active ingredient (main ingredient)	epoprostenol sodium
Other ingredients (inactive ingredients)	glycine mannitol sodium chloride sodium hydroxide water for injections

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

What FLOLAN looks like

FLOLAN is a sterile white to off white powder supplied with a diluent in the following presentations:

- 0.5 mg vial with either 1 or 2 vials of diluent and 1 filter (AUST R 80342)

- 1.5 mg vial with either 1 or 2 vials of diluent and 1 filter (AUST R 80343)

Who distributes FLOLAN

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

Phone: 1800 033 109

www.gsk.com.au

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