VELETRI®

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 using VELETRI?

VELETRI contains the active ingredient epoprosterol sodium. VELETRI is used to treat some types of pulmonary arterial hypertension (PAH).

For more information, see Section 1. Why am I using VELETRI? in the full CMI.

2. What should I know before I use VELETRI?

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.

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 use VELETRI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VELETRI 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 do I use VELETRI?

- VELETRI is intended for intravenous infusion into a vein.
- Your doctor or nurse will show you how to prepare VELETRI and how to administer it if you are using VELETRI at home.

More instructions can be found in Section 4. How do I use VELETRI? in the full CMI.

5. What should I know while using VELETRI?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using VELETRI. • Tell your doctor if you have not used VELETRI as intended. • Keep your catheter clean and the area around it clean and free from infection.
Things you should not do	• Do not stop using this medicine suddenly or change the dose without first checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how VELETRI affects you. VELTRI may cause dizziness, drowsiness or tiredness in some people.
Looking after your medicine	• Store VELETRI below 25°C in the box to protect it from light. Do not freeze. • Once VELETRI has been mixed with the diluent it should be used immediately or stored as per the conditions listed in Section 5. What should I know while using VELETRI? in the full CMI.

For more information, see Section 5. What should I know while using VELETRI? in the full CMI.

6. Are there any side effects?

Common side effects which have been reported include flushing, headache, dizziness, pain, jaw, muscle and/or back pain, joint pain, muscle tremors, increased body movement, nausea or vomiting, diarrhoea, wind or tummy discomfort, loss of appetite, facial flushing or paleness, itchy skin rash (eczema) or hives, decreased or increased feeling or sensitivity (especially in the skin), ulcer (sore) on the skin, sweating, dry mouth, fatigue, feeling very tired, anxiety, nervousness and agitation, fast or slow heart rate, fever, chills or flu-like symptoms.

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.

VELETRI®

Active ingredient(s): *epoprostenol sodium (E-poe-PROST-e-nol SOE-dee-um)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using VELETRI?

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

VELETRI 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.

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

2. What should I know before I use VELETRI

Warnings

Do not use VELETRI if:

- you are allergic to epoprostenol sodium, 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.
  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
- heart disease
- take any medicines for any other condition.

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.

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

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 VELETRI and affect how it works.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines to prevent blood clots, such as heparin, warfarin, aspirin or other anti-inflammatory pain killers (NSAIDs)
- medicines that are used to treat high blood pressure, or a group of medicines known as nitrates that are 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 VELETRI.

4. How do I use VELETRI?

How much to use

- Initial treatment with VELETRI 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 highest dose you can tolerate. During this part of the treatment you will also learn about how your body reacts to VELETRI.
- 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.
- Follow the instructions provided and use VELETRI until your doctor tells you to stop.

When to use VELETRI

- VELETRI should be used according to the dosing schedule prescribed by your doctor.
- Use VELETRI for as long as your doctor advises you to. VELETRI is generally used over a prolonged period of time, possibly years. It should not be stopped suddenly.
  Symptoms of suddenly stopping VELETRI include dizziness, weakness and difficulty breathing.

How to use VELETRI

- VELETRI infusion will be given to you as continuous 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) 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.
- Before VELETRI is used, it must be dissolved only in sterile water for injection or Sodium Chloride 0.9% solution for injection. Your doctor or nurse will also show you how to prepare and administer VELETRI and how to stop treatment if necessary. It is very important you follow their instructions carefully.
- VELETRI contains no preservative. Use a vial once only and then discard.
- The reconstituted solution should be immediately further diluted to the final concentration.
- Do not use this medicine if you notice any particles in the reconstituted solution.

If you use too much VELETRI

As VELETRI 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 VELETRI 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 VELETRI at home and you think that you have used too much, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26** in Australia. In New Zealand telephone **0800 POISON** or **0800 764 766**), 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 VELETRI?

Things you should do

- 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).
- Tell your doctor or pharmacist that you are using VELETRI if you are about to start on any new medicines.

Call your doctor straight away if you:

- your intravenous catheter becomes blocked
- you have buildup of fluid in the abdomen causing pain and swelling
- 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.

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

Things you should not do

- Do not stop using this medicine suddenly
- Do not change your dose without first checking with your doctor
- Do not give this medicine to anyone else, even if their symptoms are similar to yours
- Do not use any other piece of equipment or material to administer VELETRI 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 VELETRI affects you.

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

Looking after your medicine

- Keep VELETRI powder in a cool, dry place where it stays below 25°C and protected from light by keeping it in the carton until use.
- Do not expose diluted solution to direct sunlight.
- Do not freeze VELETRI powder at any time.

Follow the instructions in the carton on how to take care of your medicine properly.

Do not use this medicine after the expiry date.

Store it in a cool dry place 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.

Keep it where young children cannot reach it.

Do not use VELETRI if the packaging is torn or shows signs of tampering.

When to discard your medicine

VELETRI diluted to the final concentration in the drug delivery reservoir as directed can be stored for up to 8 days at 2° to 8°C. Discard any unused solution after this time. Do not freeze.

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.

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
• headache • dizziness • pain • jaw, muscle and/or back pain • joint pain • muscle tremors • increased body movement • feeling sick (nausea) or being sick (vomiting) • diarrhoea • wind or tummy discomfort • loss of appetite • facial flushing or paleness • itchy skin rash (eczema) or hives • decreased or increased feeling or sensitivity, especially in the skin • ulcer (sore) on the skin • sweating • dry mouth • fatigue, feeling very tired • anxiety, nervousness and agitation • low blood pressure • fast heart rate • slow heart rate fever, chills or flu-like symptoms • urinary tract infection • lung infection	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Symptoms of allergic reaction: • wheezing, difficulty in breathing, swelling of the lips/ mouth/tongue, hay fever, lumpy rash (“hives”) and fainting **Blood and bruising related:** • blood clot that moves to the lungs, causes chest pain and makes you short of breath • bleeding or bruising more easily than normal • low number of platelets or red blood cells or all types of blood cells **Infection-related:** • infection of the blood (septicaemia) **Heart-related:** • chest pain, feeling of tightness around the chest, heart attack • 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) **Nervous system-related:** • depression/ psychotic depression • acute confusional state **Others:** • reddening and pain at the infusion site • 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 • 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	**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.**

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

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 VELETRI contains

Active ingredient (main ingredient)	epoprostenol, as the sodium salt
Other ingredients (inactive ingredients)	sucrose L-arginine sodium hydroxide

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

What VELETRI looks like

VELETRI is a sterile, lyophilised white to off-white powder in a clear glass vial with a rubber stopper and an aluminium flip-off cap. Each pack contains one vial. The 0.5 mg vial has a white flip-off cap and the 1.5 mg vial has a red flip-off cap.

VELETRI is supplied as a pack containing one vial:

- 0.5 mg vial of epoprostenol (AUST R 208316)
- 1.5 mg vial of epoprostenol (AUST R 207547)

Who distributes VELETRI

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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