

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about this medicine, speak to your child's doctor.

1. Why is my child being treated with Prostin VR?

Prostin VR contains the active ingredient alprostadil. Prostin VR is used to keep a blood vessel called the ductus arteriosus open temporarily after your child is born. This helps some children with certain heart defects, for blood to flow around their body until their condition is treated, as usually the blood vessel closes soon after birth.

For more information, see Section [1. Why is my child being treated with Prostin VR?](#) in the full CMI.

2. What should I know before my child is treated with Prostin VR?

Talk to your doctor if your child has any other medical conditions.

For more information, see Section [2. What should I know before my child is treated with Prostin VR?](#) in the full CMI.

3. How is Prostin VR given?

Prostin VR should only be used under the supervision of healthcare professionals trained in the care of children, usually in the newborn intensive care unit. Prostin VR is diluted and given by continuous infusion (a slow drip) into the bloodstream.

More instructions can be found in Section [3. How is Prostin VR given?](#) in the full CMI.

4. What should I know while my child is treated with Prostin VR?

Your child will be closely monitored, including their breathing, heart rate and blood pressure, during treatment.

For more information, see Section [4. What should I know while my child is treated with Prostin VR?](#) in the full CMI.

5. Are there any side effects?

Tell your child's doctor or nurse straight away if you notice any of these side effects: flushing, pauses in breathing (apnea) or wheezing, fever, slow or fast heart rate, swelling, diarrhoea, fits or convulsions, bruising or uncontrolled bleeding, low volume of urine (wee) or blood in wee or stool (poo), stiffness.

There are other possible side effects that you will not notice that your doctor will monitor closely for.

For more information, see Section [5. Are there any side effects?](#) in the full CMI.

Prostin® VR

Active ingredient(s): alprostadil

Consumer Medicine Information (CMI)

This leaflet provides important information about Prostin VR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Prostin VR.**

Where to find information in this leaflet:

1. [Why is my child being treated with Prostin VR?](#)
2. [What should I know before my child is treated with Prostin VR?](#)
3. [How is Prostin VR given?](#)
4. [What should I know while my child is treated with Prostin VR?](#)
5. [Are there any side effects?](#)
6. [Product details](#)

1. Why is my child being treated with Prostin VR?

Prostin VR contains the active ingredient alprostadil.

Prostin VR is used to keep a blood vessel called the ductus arteriosus open temporarily after your child is born. Normally, this blood vessel closes soon after birth. In some children who are born with heart defects, this blood vessel needs to be kept open for a longer time so that enough blood can reach the rest of the body. Once the child's heart defect is treated, Prostin VR is usually no longer needed and the blood vessel should close.

Your doctor may prescribe Prostin VR for other reasons. Ask your doctor if you have any questions about why Prostin VR has been prescribed for your child.

2. What should I know before my child is treated with Prostin VR?

Some information is given below. Talk to your doctor if you have any concerns or questions about your child's treatment.

Prostin VR should not be given in:

- Children with the following medical conditions:
 - o a blue appearance of the skin, lips and nails due to poor blood flow through the lungs
 - o abnormal or unusual blood flow between the lungs and the heart

Check with your doctor if:

- Your child has had any medical conditions, especially the following:
 - o history of bleeding tendencies
 - o a breathing problem where the lungs have difficulty holding in air (respiratory distress syndrome).

During treatment, your child should be closely monitored for certain side effects. See additional information under Section [5. Are there any side effects?](#)

3. How is Prostin VR given?

How it is given

- Prostin VR should only be used under the supervision of healthcare professionals trained in the care of children, usually in the newborn intensive care unit.
- Prostin VR is diluted and given by continuous infusion (as a slow drip) into the bloodstream.
- Your child's breathing, heart rate and blood pressure will be closely monitored while Prostin VR is being given.

How much is given

- Your child's doctor will decide what dose will be given.
- Prostin VR Injection is generally not given for more than 2-3 days at a time. It will be given for the shortest time possible to treat your child properly. Treatment courses may be repeated more than once.
- Treatment will usually start within 4 days after birth.

If too much Prostin VR is given (overdose)

Overdose is unlikely as treatment will be given by trained healthcare professional. Your child will be closely monitored during treatment. Your doctor has information on how to recognise and treat an overdose. The possible side effects of overdose are the same as those listed below under 5. Are there any side effects?, and particularly fever and flushing.

4. What should I know while my child is treated with Prostin VR?

Your child will be closely monitored, including their breathing, heart rate and blood pressure, during treatment. Immediately inform your child's doctor or nurse straight away if you notice any of the symptoms listed in 5. Are there any side effects? below.

5. Are there any side effects?

All medicines can have side effects. Your child will be closely monitored for any signs of side effects during treatment of Prostin VR.

See the information below and ask your doctor or nurse if you have any further questions about side effects.

Side effects that you may notice

Side effects	What to do
• flushing • pauses in breathing (apnea) or wheezing	Inform your child's doctor straight away if

Side effects	What to do
• fever • slow or fast heart rate • swelling • diarrhoea • fits or convulsions • bruising or uncontrolled bleeding • low volume of urine (wee) or blood in wee or stool (poo) • stiffness	you notice any of these side effects.

Additional side effects that your child's doctor will also monitor for

Side effects	What to do
• heart problems including heart attack • infections • low blood pressure • problems with the blood including low blood cells, low or high potassium, • low blood sugar • problems with the lungs, kidneys (including kidney failure), digestive system and certain bones • low body temperature • excessive irritability • breathing problems • unusual extension of the neck	Your child's doctor will monitor for any of these side effects.

Tell your doctor or pharmacist if you notice anything else in your child. Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

6. Product details

This medicine is only available with a doctor's prescription and administered by a healthcare professional only.

What Prostín VR contains

Active ingredient (main ingredient)	alprostádil
Other ingredients (inactive ingredients)	ethanol

Prostín VR does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Prostín VR looks like

Prostín VR is a sterile, clear, colourless solution for infusion. It is available in a 500 micrograms/mL strength ampoule. (AUST R 47641)

How is Prostín VR stored

Prostín VR will normally be stored under the correct conditions in the hospital.

Who distributes Prostín VR

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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