

Prostin(R) VR

Alprostadi

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prostin VR.

It does not contain all the available information and 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 your child being given Prostin VR against the benefits they expect it to provide your child.

If you have any concerns about your child being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with you.

You may need to read it again.

What Prostin VR is used for

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 has been fixed or treated, s/he will not usually need to be given Prostin VR any more, 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.

Before your child is given Prostin VR

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

When your child must not be given Prostin VR

Children with the following medical conditions must not be given Prostin VR:

- * a blue appearance of the skin, lips and nails due to poor blood flow through the lungs
- * abnormal or unusual blood flow between the lungs and the heart

Before your child is given Prostin VR

Your child should only be given Prostin VR by qualified medical staff. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled personnel.

Tell your doctor if your child is being given any other medicine, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if your child has had any medical conditions, especially the following:

- * history of bleeding tendencies
- * a breathing problem where the lungs have difficulty holding in air (respiratory distress syndrome).

How Prostin VR is given

Prostin VR will be given to your child by a doctor, nurse, or other trained person. It is diluted and given by continuous infusion into the bloodstream.

Your child's 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.

Overdose

Overdose is unlikely as treatment will be given by trained medical personnel. Your doctor or pharmacist has information on how to recognise and treat an overdose. The possible side effects of overdose are the same as those listed below under Side Effects.

Side effects

Prostin VR, like all other medicines, may cause unwanted side effects. Sometimes they are serious, often they are not.

Common side effects (occurring in 10-15% of patients) are:

- * Flushing
- * Temporarily stopping breathing
- * Fever

Less common side effects (occurring in less than 10% of patients) include:

- * Slow or fast heart rate
- * Low blood pressure
- * Swelling
- * Heart attack
- * Diarrhoea
- * Fits or convulsions
- * Increased blood clotting
- * Low potassium in the blood
- * Infection

This is not a complete list of side effects. Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of side effects. Your child may not experience any of them.

Ask your doctor to answer any questions you may have.

After using Prostin VR

Storage

Prostin VR will normally be stored in the hospital where it is stored in the refrigerator (2 degrees C to 8 degrees C). Unused ampoules of Prostin VR are stored in the refrigerator. Prostin VR must not be frozen.

After dilution, Prostin VR should be used as soon as possible. If storage is necessary after dilution, then it should be stored in a refrigerator (2 degrees C to 8 degrees C). Any solution not used within 24 hours after dilution should be discarded.

Product description

What it looks like

Prostin VR is a sterile, clear, colourless solution for infusion. It is available in a 500 micrograms/mL strength glass ampoule, and each box contains 5 ampoules.

Ingredients

The active ingredient in Prostin VR is alprostadil (Prostaglandin E1).

Prostin VR also contains ethanol.

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

Prostin VR can be identified by an Australian Registration Number which appears on the box:

AUST R 47641

Supplier

Prostin VR is supplied in Australia by:

Pfizer Australia Pty Ltd:
ABN 50 008 422 348:
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll free number: 1800 675 229

This leaflet was revised in September 2005.