

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROSTIN VR[®], 0,5 mg/ml sterile solution

Alprostadil

Sugar Free

Read all of this leaflet carefully before your baby receives PROSTIN VR

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PROSTIN VR has been prescribed for your baby and should not be shared with anybody else. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PROSTIN VR is and what it is used for
2. What you need to know before you are given PROSTIN VR
3. How to use PROSTIN VR
4. Possible side effects
5. How to store PROSTIN VR
6. Contents of the pack and other information

1. What PROSTIN VR is and what it is used for

PROSTIN VR contains the active substance alprostadil. Alprostadil is a synthetic copy of a prostaglandin chemical that occurs naturally in your body.

Prostaglandins are a complex set of chemicals made by the body tissues. Some of them can cause

muscles, which occur in the walls of certain blood vessels, to relax.

PROSTIN VR is a medicine given to newborn babies through an injection into the vein or a catheter (fine tube) into an artery.

While a baby is in the womb, before it is born, it does not breathe. For this reason, in a baby's heart there is a special, small blood vessel called the ductus arteriosus that allows blood to pass through the heart without going through the lungs. Once the baby is born and breathing normally, this is no longer needed, and the ductus arteriosus would close off.

If the baby has certain conditions affecting the heart it may still be beneficial to keep this channel (the ductus arteriosus) open until the heart condition can be corrected by surgery. This is what PROSTIN VR can do i.e. it relaxes the muscles in the wall of the ductus arteriosus while the baby still requires this. Once the baby has had an operation to correct the heart problem, then the ductus arteriosus will no longer be needed and can be allowed to close.

Your baby may have one of several problems in which it is necessary to keep the ductus arteriosus open until an operation can take place. Your baby's doctor will explain which problem affects your baby.

2. What you need to know before you are given PROSTIN VR

Children

PROSTIN VR contains alcohol (ethanol) and is likely to affect children (see PROSTIN VR contains alcohol (ethanol)). All babies can have PROSTIN VR if they really need it. The doctor will carry out tests before deciding whether to give PROSTIN VR to your baby.

PROSTIN VR should not be given if:

Your baby is hypersensitive (allergic) to alprostadil or any of the other ingredients of (PROSTIN VR listed in section 6). The symptoms of an allergic reaction can be the following: wheezing, breathlessness, swelling of the face, hands, itchy rash or redness of the skin.

Warnings and precautions

Take special care with PROSTIN VR:

- if your baby has a tendency to bleed easily. The doctor will be cautious when using PROSTIN VR as it may prevent blood from clotting properly.
- if your baby suffers from an obstruction of the blood flow into the lungs, blood will be flowing through the ductus arteriosus from the main artery of the lungs. In this case, PROSTIN VR can be given through a catheter (fine tube) placed at or just above the junction between the main artery and the ductus arteriosus or can be given intravenously (by a drip into a vein).
- if your baby develops interrupted breathing (apnoea) or a slow heartbeat, PROSTIN VR should be stopped, and appropriate medical treatment should be given. This most often occurs in babies weighing less than 2 kg at birth. It usually happens within the first hour of the medicine being given. Doctors and nurses will watch your baby carefully in case they need to ventilate him or her (give oxygen) until normal breathing starts again. PROSTIN VR will only be used where there are facilities to do this. If the baby develops a high temperature or low blood pressure, PROSTIN VR should be given at a slower rate until these symptoms subside.
- if your baby suffers from feeding problems. PROSTIN VR may cause thickening of the stomach wall, such that emptying of the stomach contents may be difficult. This effect has been linked with the total amount of medicine given and the length of time it is given for. If your baby is given PROSTIN VR for more than 120 hours, the doctor will watch carefully for this problem which will cause the baby to vomit after feeds.
- if PROSTIN VR is given for a very long time period the walls of the ductus arteriosus and of the artery that connects the heart to the lungs (pulmonary artery) may weaken.

- PROSTIN VR may cause abnormalities of long bones. Your doctor will monitor your baby's symptoms and may decide if PROSTIN VR needs to be withdrawn.
- if your baby has respiratory distress syndrome (hyaline membrane disease). PROSTIN VR must not be used in babies with this condition therefore your baby's doctor will ensure correct diagnosis.

Children and adolescents

PROSTIN VR contains a quantity of alcohol that is likely to affect children

Other medicines and PROSTIN VR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Babies born with heart problems usually have to be given several different medicines. These medicines may be to:

- improve the pumping action of the heart. These medicines act directly on the heart muscle and belong to a group of medicines called cardiac glycosides, e.g. digoxin.
- raise the blood pressure, e.g. dopamine or isoproterenol.
- reduce the volume of the blood and hence the workload on the heart. These medicines are called diuretics or water tablets, e.g. furosemide.
- fight infections (antibiotics), e.g. penicillin or gentamicin.

PROSTIN VR can be given at the same time as these medicines as no interactions with these medicines have been reported.

PROSTIN VR with food, drink and alcohol

PROSTIN VR contains alcohol (ethanol).

Your doctor will take this into account when deciding to give PROSTIN VR to your baby.

PROSTIN VR contains 790 mg alcohol (ethanol) in each 1 mL vial which is equivalent to 790 mg/mL (79 % w/v). The amount of alcohol in each 1 mL vial is equivalent to less than 20 mL beer or 8 mL wine.

The amount of alcohol in PROSTIN VR is likely to affect children. These effects may include feeling sleepy and changes in behaviour.

Because this medication is administered slowly over 24 hours the effects of ethanol may be reduced.

Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, particularly in young children with low or immature metabolic capacity.

If your baby suffers from epilepsy or liver problems, talk to your doctor or pharmacist before taking PROSTIN VR

The amount of alcohol in PROSTIN VR may alter the effects of other medicines. Talk to your doctor or pharmacist if your baby is taking other medicines.

Pregnancy and breastfeeding

Not applicable

Driving and using machines

Not applicable

3. How to use PROSTIN VR

Do not share medicines prescribed for you with any other person.

Always use PROSTIN VR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PROSTIN VR will be given to your baby by a doctor or a nurse.

PROSTIN VR must only be given by a doctor in a hospital or in a place where intensive care facilities are immediately available if needed.

PROSTIN VR can be given by an intravenous drip or through an artery by way of a tube (catheter). The small volume (1 mL of medicine must be diluted with larger volumes of a special salt or sugar solution. The amount of solution used will depend on how the medicine is to be given.

Different babies need different amounts of PROSTIN VR. Your doctor will give the smallest amount needed for the shortest length of time to give a good result. The doctor will have carefully worked out the risks of giving the medicine over a long period in a very ill baby, against the possible benefits that the baby will get from the treatment or the risks of reducing or stopping PROSTIN VR treatment early.

As soon as tests show that the baby is responding, the rate will be reduced to the lowest possible dose that will maintain the response. (If your baby has an obstruction to the flow of blood to the lungs, the doctor will be looking for an increase in the amount of oxygen in the blood; if your baby has an obstruction in the flow of blood to the rest of the body, the doctor will be looking for an increase in the blood pressure and a fall in the acidity of the blood).

As soon as the baby starts to have the medicine, the pressure of the blood in the arteries will be checked at regular intervals. As PROSTIN VR relaxes muscles in other blood vessels this may cause a lowering of the baby's blood pressure. In order to do this, the doctor may use the catheter through which the medicine is being given, or a stethoscope or an ultrasound device. If pressure falls significantly, the rate at which PROSTIN VR is being given will be reduced straight away.

If you have any further questions on the use of PROSTIN VR, as your baby's doctor or nurse.

Your doctor will tell you how long your treatment with PROSTIN VR will last. If you have the impression that the effect of PROSTIN VR is too strong or too weak, tell your doctor or pharmacist.

If your baby is given more PROSTIN VR than should be given

Since a health care provider will administer PROSTIN VR, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a dose of PROSTIN VR has been forgotten

Since a health care provider will administer PROSTIN VR, it is unlikely that the dose will be missed.

4. Possible side effects

PROSTIN VR can have side effects.

Not all side effects reported for PROSTIN VR are included in this leaflet. Should your general health worsen or if you experience any untoward effects during or after receipt of PROSTIN VR, please consult your health care provider for advice.

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects – your baby may

need urgent medical treatment:

- interrupted breathing (apnoea)
- a high temperature for a short time period (transient pyrexia).

Tell your doctor if you notice any of the following:

Frequent side effects:

- flushing of the skin. This happens more often when the medicine is given by catheter into an artery and is usually relieved by repositioning the tip of the catheter
- a heartbeat that is slower than normal (bradycardia)
- low blood pressure
- a heartbeat that is faster than normal (tachycardia)
- stopping of the heart
- swelling caused by too much fluid in the body.
- fits (seizures)

Other side effects:

- heart failure
- increase of blood flow to different tissues in the body
- abnormal heart rhythm
- bleeding between the brain tissue and the skull or inside the brain tissue
- hyperextension of the neck
- shock
- increased irritability
- increases sleepiness or lack of energy
- decreased size of baby's head
- stiffness
- abnormally slow breathing rate

- wheezing
- difficulty breathing
- shortness of breath
- rapid and shallow breathing
- diarrhoea
- liver disease (symptoms include a yellowish coloration of the skin and whites of the eyes (jaundice), abnormally pale stools, and dark urine.
- gastric regurgitation (stomach acid repeatedly flows back up into the tube connecting the mouth and stomach)
- clotting and bleeding throughout the circulation (disseminated intravascular coagulation)
- anaemia (low levels of healthy red blood cells to carry oxygen throughout your body). Symptoms include tiredness, weakness and shortness of breath.
- bleeding
- reduced urine output
- decreased kidney function
- sudden decrease in response to medicine
- sepsis (body's response to infection causes injury to its own tissues and organs)
- redness and swelling (inflammation) of the lining of your belly or abdomen.
- high or low potassium levels in the blood
- low level of glucose in your blood

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PROSTIN VR.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com

5. How to store PROSTIN VR

- Store all medicines out of reach of children
- Do not use PROSTIN VR after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C)
- Diluted solutions should be used within 24 hours
- Store in the original package in order to protect from light
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g, toilets)

6. Contents of the pack and other information

What PROSTIN VR contains

- The active substance is alprostadil. Each ampoule contains 500 milligrams of alprostadil.
- The other ingredient is ethanol (see section 2 PROSTIN VR contains alcohol (ethanol)).

What PROSTIN VR looks like and contents of the pack

PROSTIN VR is a clear, colourless, sterile concentrate for solution for infusion contained in 1 mL glass ampoules.

PROSTIN VR is available in multipacks of 5 x 1 mL ampoules.

Holder of Certificate of Registration

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