

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr **PROSTIN* VR STERILE SOLUTION**
(alprostadil injection USP)

Read this carefully before your baby receives **PROSTIN VR STERILE SOLUTION**. This leaflet is a summary and will not tell you everything about this drug. Talk to your baby's healthcare professional about your baby's medical condition and treatment and ask if there is any new information about **PROSTIN VR STERILE SOLUTION**.

Serious Warnings and Precautions

About 10 to 12% of newborns that received PROSTIN VR STERILE SOLUTION had interrupted breathing (apnea). Apnea is seen most often in newborns weighing less than 2 kg at birth. It usually appears during the first hour of drug infusion. PROSTIN VR STERILE SOLUTION should be used by trained healthcare professionals in places where your baby has access to the proper equipment for intensive care.

What is PROSTIN VR STERILE SOLUTION used for?

PROSTIN VR STERILE SOLUTION is used in newborns that have congenital heart defects. It is used to keep a blood vessel called the ductus arteriosus open for a short time after your child is born. The ductus arteriosus is a temporary blood vessel found in unborn babies. It normally closes soon after birth. For babies born with some congenital heart defects this blood vessel needs to be kept open for a longer time until surgery can be done to fix or treat the heart condition.

How does PROSTIN VR STERILE SOLUTION work?

PROSTIN VR STERILE SOLUTION relaxes the muscle in the wall of the ductus arteriosus to keep it open while the newborn needs it.

What are the ingredients in PROSTIN VR STERILE SOLUTION?

Medicinal ingredient: alprostadil

Non-medicinal ingredient: anhydrous ethanol

PROSTIN VR STERILE SOLUTION comes in the following dosage form:

Solution for injection: 0.5 mg / mL

Your newborn must not receive PROSTIN VR STERILE SOLUTION if he or she:

- Has blueness or lividness of the skin with persistent pulmonary hypertension.
- Has a rare congenital defect of the pulmonary veins.
- Has multiple small accessory spleens or absence of normal spleen function in whom the pulmonary valve of the heart does not form properly and that have a rare heart defect that occurs when the pulmonary veins fail to form normally.

To help avoid side effects and ensure proper use, talk to your newborn's healthcare professional before your newborn takes PROSTIN VR STERILE SOLUTION. Talk about any health conditions or problems he or she may have, including:

- Respiratory distress syndrome (a breathing problem that makes it hard for your baby to breath)
- Weakening of the temporary blood vessel (ductus arteriosus) and of the arteries going from the heart to lungs
- Bone and tissue changes
- A history of bleeding tendencies

Other warnings you should know about:

Increased cell reproduction at the lower part of the stomach (antral hyperplasia): PROSTIN VR STERILE SOLUTION may cause an increase in cell reproduction at the lower part of your newborn's stomach if it given for more than 5 days. This can cause a blockage between the stomach and the small intestine. Your newborn's doctor will closely monitor your baby for this condition if PROSTIN VR STERILE SOLUTION is given for more than 5 days.

Tell your newborn's healthcare professional about all the medicines he or she takes, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How PROSTIN VR STERILE SOLUTION will be given:

PROSTIN VR STERILE SOLUTION is to be used:

- by a trained healthcare professional
- in a place with the proper equipment available to your baby for intensive care

Treatment will usually start within 4 days after birth. It will be given for the shortest time possible to treat your baby properly.

It will be given to your baby as a continuous infusion into either their:

- vein (intravenously) or
- umbilical artery through a long, soft, hollow tube (called a catheter)

Your newborn's blood pressure will be closely monitored while PROSTIN VR STERILE SOLUTION is being given.

Usual dose:

Your newborn's doctor will decide the dose and for how long PROSTIN VR STERILE SOLUTION will be given.

Overdose:

If you think your baby has been given too much PROSTIN VR STERILE SOLUTION, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Signs of an overdose include:

- interrupted breathing (apnea)
- a slow heart rate
- fever
- low blood pressure
- flushing

What are possible side effects from using PROSTIN VR STERILE SOLUTION?

These are not all the possible side effects your baby may feel when taking PROSTIN VR STERILE SOLUTION. If your baby experiences any side effects not listed here, contact your healthcare professional.

Side effects include:

- flushing
- fever
- feeling irritable
- feeling tired or sleepy
- feeling jittery
- stiffness
- diarrhea
- gastric regurgitation

Serious side effects and what to do about them			
Symptom / effect	Talk to your baby's healthcare professional		Stop the drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Apnea (Interrupted breathing)			✓
COMMON			
Bradycardia (slower than normal heartbeat): dizziness, feeling tired, shortness of breath, chest pains, memory problems			✓
Hypotension (low blood pressure): dizziness or lightheadedness, fainting, blurred vision, nausea, feeling tired.			✓
Tachycardia (faster than normal heartbeat): shortness of breath, lightheadedness, rapid pulse rate, irregular heartbeat, chest pain, fainting.			✓
Cardiac arrest			✓
Edema: swelling of the arms and legs			✓

Seizure			✓
Disseminated intravascular coagulation (a condition in which blood clots form throughout the body, blocking small blood vessels): bleeding which may be severe			✓
Sepsis (serious infection that causes your immune system to attack your body)			✓
Hypokalemia (low level of potassium in the blood): muscle weakness, feeling tired and muscle cramps			✓
UNCOMMON/RARE			
Congestive heart failure (a condition in which the heart can't pump enough blood): shortness of breath, feeling tired, weakness, swelling in your legs, ankle and feet, rapid or irregular heartbeat			✓
Spasm of the right infundibulum [conus arteriosus] (upper right ventricle of the heart)			✓
Second degree heart block (a disease of the electrical conduction system of the heart)			✓
Ventricular fibrillation (heart rhythm problem that occurs when the heart beats with rapid, erratic electrical impulses): chest pain, rapid heartbeat, dizziness, shortness of breath, loss of consciousness			✓
Ventricular hypertrophy (enlargement and thickening of the walls of the heart (left ventricle)): shortness of breath, feeling tired, sensation of rapid, fluttering or pounding heartbeats, dizziness or fainting			✓
Intracranial bleeding (bleeding in the brain): sudden, extremely severe headache			✓
Hypothermia (abnormal low body temperature): shivering,			✓

slow, shallow breathing; slurred speech, drowsiness, confusion or memory loss, loss of consciousness			
Shock (a sudden drop in blood flow through the body): cool, clammy skin, paleness, rapid pulse, rapid breathing, nausea or vomiting, enlarged pupils, weakness, dizziness or fainting			✓
Bradypnea (abnormally slow breathing): lightheadedness, dizziness, feeling tired			✓
Pneumothorax (collapsed lung): sudden chest pain and shortness of breath			✓
Difficulty breathing			✓
Jaundice (liver condition that causes yellowing of a newborn's skin and eyes)			✓
Peritonitis (inflammation of the membrane covering the inside of the abdomen and its organs): abdominal pain, bloating, fever, nausea and vomiting, loss of appetite, diarrhea, thirst, inability to pass stool or gas, feeling tired			✓
Peritonsillitis (inflammation of the connective tissue above and behind the tonsil): fever, chills, difficulty swallowing or opening the mouth fully, swelling of the face and neck, headache			✓
Thrombocytopenia (low levels of platelets in the blood): easy or excessive bruising, a rash of pinpoint-sized reddish-purple spots usually on the legs, prolonged bleeding from cuts, bleeding from the gums or nose			✓
Anuria (failure of the kidneys to produce urine)			✓
Hematuria (blood in the urine)			✓
Whiplash (hyperextension of the neck)			✓
Bronchial wheezing: a high-pitched whistling sound while breathing.			✓

Hyperkalemia (high level of potassium in the blood): feeling tired or weak, a feeling of numbness or tingling, nausea or vomiting, chest pain, irregular heartbeats			✓
Anemia (low levels of red blood cells in the blood): feeling tired, weakness, pale or yellowish skin, shortness of breath, dizziness or lightheadedness, chest pain, irregular heartbeats			✓
Hypoglycemia (low blood sugar): feeling tired, pale skin, sweating, chills and clammy skin, feeling shaky, confusion, fast heartbeat, feeling weak or having no energy			✓
Hypercapnia (too much carbon dioxide in the blood): flushed skin, drowsiness, headache, feeling dizzy, shortness of breath, feeling exhausted			✓
Hyperemia (excess blood in parts of your body)			✓
Pneumopericardium (air entering the cavity surrounding the heart): chest pain, rapid heart rate, pain in the upper abdomen, nausea, shortness of breath, fainting, drop in blood pressure			✓
Tachyphylaxis (a decrease in response to the medicine)			✓
Hypoventilation: bluish colour of the skin, feeling tired			✓
Tachypnea (abnormally rapid breathing)			✓

If your baby has a troublesome symptom or side effect that is not listed here or their side effects worsen, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your baby's health professional if you need information about how to manage her or his side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

PROSTIN VR STERILE SOLUTION will be stored in the refrigerator (2°C - 8°C) by your healthcare professional.

If you want more information about PROSTIN VR STERILE SOLUTION:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<http://www.pfizer.ca>), or by calling 1-800-463-6001.

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