PEDEA®

Ibuprofen 5 mg/mL solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about Pedea.

It does not contain all of the available information. It does not take the place of talking to your baby's doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your baby taking Pedea against the benefits he/she expects it will have for your baby.

If you have any concerns about your baby taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read this again.

What PEDEA is used for

Pedea is used in premature babies to close the patent ductus arteriosus.

While a baby is inside its mother's womb it does not need to use its lungs. An unborn baby has a blood vessel called a 'ductus arteriosus' near the heart which allows the baby's blood to bypass its lungs and circulate to the rest of its body.

When the baby is born and starts using its lungs the ductus arteriosus normally closes up. However, in some cases this does not happen.

The doctor has prescribed Pedea for your baby because your baby has a ductus arteriosus which has not closed properly. Pedea can help close this blood vessel.

If the ductus arteriosus remains open, blood intended for the body may be returned to the lungs, overloading the lung's blood vessels, making the lungs and heart work harder to pump blood to the rest of the body. This can lead to failure to gain weight, shortness of breath, a fast heart rate, frequent chest infections, and sometimes heart failure.

Pedea belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines can be used to treat swelling, redness, pain and fever.

Pedea works by stopping the production of prostaglandin, a naturally occurring chemical in the body which keeps the ductus arteriosus open.

The reduction of these levels by Pedea is essential for the treatment of PDA.

Ask your doctor if you have any questions about why Pedea has been prescribed for your baby.

This medicine is available only with a doctor's prescription.

Before your doctor gives your baby PEDEA

When your baby must not be given it

Pedea should not be given to your baby if:

- Your baby has a life threatening infection
- Your baby has bleeding, especially in the brain or stomach
- Your baby has blood clotting problems
- Your baby has low blood platelet count
- Your baby has or is suspected of having an intestinal problems, called necrotising enterocolitis
- Your baby has severe kidney problems
- Your baby has heart disease at birth and it is necessary for them to have a patent ductus arteriosus for satisfactory blood flow in the lungs and throughout the body
- Your baby is allergic to ibuprofen or other ingredients in PEDEA

PEDEA should not be given if:

- The packaging is torn or shows signs of tampering
- The expiry date (EXP) printed on the pack has passed

If the medicine is given after the expiry date has passed, it may not work

Your baby's doctor will be aware of these, but if you are worried or confused, please talk to the doctor treating your baby.

Before your baby is given it:

There are other things regarding PEDEA which the baby's doctor should know about.

Do not use PEDEA if:

1. Your baby has allergies to:
   - Any other medicines including aspirin or other NSAID medicines
   - Any other substances, such as foods, preservatives or dyes
2. Your baby has high bilirubin levels in their blood

Taking Other Medicines

There are certain medicines, which if given together with PEDEA, may cause unwanted effects. These include:

- Aspirin, or other NSAIDs
- Diuretics, also called fluid or water tablets
- Blood thinners such as warfarin, heparin
- Antibiotics called aminoglycosides, such as gentamicin
- Corticosteroids such as prednisolone
- Nitric oxide

These medicines may be affected by PEDEA, or may affect how well it works. Your baby may need to take different, or use different amounts of medicines.

Your baby's doctor will be aware of the effects of PEDEA and the effects these medicines can have on each other, but if you are worried or confused, you should talk to the doctor.

How PEDEA is given

Babies with patent ductus arteriosus are cared for in a special newborn intensive care unit where the baby's condition is closely monitored.

Your baby will be given Pedea by a doctor or nurse, who will know how to make up the injection.

The doctor will decide what dose and how many courses of treatment are required. This depends on your baby's condition and other factors, such as their age and weight.

Once the ampoule containing the Pedea solution has been opened, any unused portion of the solution should be discarded.

How long Pedea is given for

One course of PEDEA treatment is given as three infusions, each 24 hours apart. If the ductus arteriosus does not close 48 hours after the last injection or if it re-opens, a second course may be given.

If the condition is unchanged after the second course of therapy, surgery of the patent ductus arteriosus may then be necessary.

While your baby is taking PEDEA

Before administration of Pedea, your doctor will perform a sonogram of your baby's heart in order to detect a patent ductus arteriosus and to exclude other conditions.

Your doctor may ask you to have your baby's kidney and gastrointestinal functions, and blood tested from time to time to make sure the medicine is working and to prevent unwanted side effects.

Pedea may inhibit blood cells which help blood to clot, so premature newborn babies should be monitored for signs of bleeding.

If your baby has also been prescribed aminoglycosides (a group of antibiotics), the doctor may need to do tests regularly to check the blood levels of the antibiotic.

If your baby has taken more Pedea than he should, or if children have taken medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also, agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If your baby is about to be started on any new medication, remind your doctor and pharmacist that they are taking Pedea.

Tell any other doctors, dentists and pharmacists who treat your baby that they are taking this medicine.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your baby may need medical treatment if they get some of the side effects.

Do not be alarmed by the list of possible side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Your baby may not experience any of them.

Tell your doctor if

Tell your doctor, pharmacist or nurse immediately if you notice any of the following:

- Signs of stomach bleeding (e.g. bleeding from the back passage, black sticky bowels or bloody diarrhea, vomiting blood or material that looks like coffee grounds)
- Blood in the urine
- Any other unusual bleeding or bruising
- Gastrointestinal disturbances (e.g. vomiting, stomach bloating, diarrhea)
- Fluid retention or swelling
- Slow heart beat
- Low blood pressure
- Abnormal kidney function (e.g. passing less urine than normal)
- Serious skin reactions, skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis)

Storage

PEDEA will be stored in the hospital pharmacy or on the ward.

It is kept where the temperature stays below 30°C.

Disposal

Once the ampoule containing the Pedea solution has been opened, any unused portion of the solution should be discarded.

Product Description

What it looks like

Pedea 5 mg/ml, solution for injection is dispensed in a 2 ml colourless glass ampoule. Each pack contains four ampoules.

Pedea 5 mg/mL solution for injection is a colourless to slightly yellow solution. Each mL contains 5 mg of ibuprofen.

Ingredients

The active ingredient of Pedea is ibuprofen.

The other ingredients are:

- Trometamol
- Sodium hydroxide
- Sodium chloride
- Hydrochloric acid
- Water for injection
- Nitrogen (in the headspace within the ampoules).

This medicine does not contain lactose or gluten.

Supplier

Pedea is supplied in Australia by:

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