

### Consumer Medicine Information (CMI) summary

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

#### 1. What is PEDEA® used for?

PEDEA® contains the active ingredient Ibuprofen. PEDEA® is used in premature babies to close the patent ductus arteriosus. For more information, see Section [1. What is PEDEA® used for?](#) in the full CMI.

#### 2. Before your baby is given PEDEA®

Do not give PEDEA® if your baby has ever had an allergic reaction to ibuprofen or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if your baby has any other medical conditions or takes any other medicines.**

For more information, see Section [2. Before PEDEA® is given](#) in the full CMI.

#### 3. Taking other medicines

Some medicines may interfere with PEDEA® and affect how it works.

A list of these medicines is in Section [3. Taking other medicines](#) in the full CMI.

#### 4. How is PEDEA® given?

- The doctor will decide what dose and how many courses of treatment are required.

More instructions can be found in Section [4. How PEDEA® is given](#) in the full CMI.

#### 5. While your baby is taking PEDEA®

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist treating your baby that they are taking PEDEA®</li><li>• Monitor your baby for side effects</li><li>• Remind any doctor, dentist or pharmacist treating your baby if they are taking other medicines or have any medical conditions they have</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Give PEDEA® to your baby if they are allergic to ibuprofen</li><li>• Give PEDEA® if the packaging is torn or shown sign of tampering</li><li>• Give PEDEA® if the expiry date has passed</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• PEDEA® will be stored in the hospital pharmacy or on the ward.</li><li>• It is kept where the temperature stays below 30°C.</li></ul>

For more information, see Section 5. Before PEDEA® is given in the full CMI.

#### 6. Are there any 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. Some of the serious side effects are slow heart beat, blood in the urine, unusual bleeding or bruising, abnormal kidney functions and serious skin reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# PEDEA®

Active ingredient(s): *Ibuprofen*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. What is PEDEA® used for?](#)
- [2. Before your baby is given PEDEA®](#)
- [3. Taking other medicines](#)
- [4. How is PEDEA® given?](#)
- [5. While your baby is taking PEDEA®](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. What is PEDEA® used for?

PEDEA® contains the active ingredient **Ibuprofen**.

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 Pedeia has been prescribed for your baby.**

## 2. Before your baby is given PEDEA®?

### Warnings

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

**Do not use PEDEA® if:**

- Your baby is allergic to *Ibuprofen*, or any of the ingredients listed at the end of this leaflet.
- Your baby has allergies to:
  - Any other medicines including aspirin or other NSAID medicines
  - Any other substances, such as foods, preservatives or dyes
- Your baby has high bilirubin levels in their blood
- 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 problem, 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

Always check the ingredients to make sure you can use this medicine.

**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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## 3. Taking other medicines

Tell your doctor or pharmacist if your baby is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your baby is taking and if these affect PEDEA®.**

## 4. How PEDEA® is given

### How much to use

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.

### When to use PEDEA®

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

### How long is PEDEA® 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.

## 5. 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.

**Remind any doctor, dentist or pharmacist who treat your baby that they are taking this medicine.**

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

### If your baby is given too much Pedea

If your baby has taken more PEDEA® than they 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.

**You should immediately:**

- phone the Poisons Information Centre
- (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

The symptoms of overdose can include nausea, stomach pain, vomiting (maybe 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, excess acid in the blood, low levels of potassium in your blood, cold body feeling, inability of kidneys to work properly 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.

### Looking after your medicine

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

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

## 6. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Your baby may not experience any of them



## **Who distributes PEDEA®**

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