Package leaflet: information for the user

Pedea 5mg/ml solution for injection
Ibuprofen

Read all of this leaflet carefully before this medicine is administered to your baby because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your baby. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your baby's.
- If your baby gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What pedea is and what it is used for

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 the *ductus arteriosus* near the heart which allows the baby's blood to bypass the lungs and circulate to the rest of the body.
When the baby is born and starts using its lungs the *ductus arteriosus* normally closes. However, in some cases this does not happen. The medical term for this condition is 'patent *ductus arteriosus'*, i.e. an open *ductus arteriosus*. This can cause heart problems in your baby. This condition is much more frequent in premature newborn than in full-term newborn infants.
Pedea, when given to your baby, can help to close the *ductus arteriosus*.

The active substance in Pedea is ibuprofen. Pedea closes the *ductus arteriosus* by inhibiting the production of prostaglandin, a naturally occurring chemical in the body which keeps the *ductus arteriosus* open.

2. What you need to know before pedea is administered to your baby

Pedea will only be given to your baby in a special neonatal intensive care unit by qualified health care professionals.

Do not use Pedea
- if your baby is allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6);
- if your baby has a life-threatening infection which has not been treated;
- if your baby is bleeding, especially if the bleeding is inside the skull or in the intestines;
- if your baby has a decrease of blood cells called platelets (thrombocytopenia) or other problems with their blood clotting;
- if your baby has kidney problems;
- if your baby has other problems with their heart which require the *ductus arteriosus* to remain open so that adequate circulation of the blood is maintained;
- if your baby has or is suspected to have certain problems with their intestines (a condition called necrotising enterocolitis);

Warnings and precautions
Talk to your doctor or pharmacist before Pedea is administered to your baby
- Before treatment with Pedea, your baby's heart will be examined to confirm that the ductus arteriosus is open.
- Pedea should not be given in the first 6 hours of life.
- If your baby is suspected of having liver disease, signs and symptoms of which include yellowing of the skin and eyes.
- If your baby is already suffering from an infection that is being treated, the doctor will treat your baby with Pedea only after careful consideration of your baby's condition.
- Pedea should be carefully administered to your baby by the healthcare professional, to avoid damage to the skin and surrounding tissues.
- Ibuprofen may reduce the ability of your baby's blood to clot. Your baby should therefore be watched for signs of prolonged bleeding.
- Your baby may develop some bleeding from the intestines and the kidneys. To detect this, your baby's stools and urine may be tested to determine if there is any blood present in them.
- Pedea may reduce the amount of urine your baby passes. If this is significant, your baby's treatment may be stopped until the volume of urine returns to normal.
- If your baby is taking Pedea for longer than the recommended time or at higher than recommended doses your baby is at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your baby's blood. These can be fatal (see section 4).
- Pedea may be less effective in very premature babies less than 27 weeks of gestational age.
- Serious skin reactions have been reported in association with Pedea treatment. You should stop taking Pedea and seek medical attention immediately, if you develop any 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. See section 4.

Other medicines and Pedea
Tell your doctor or pharmacist if your baby is taking, have recently taken or might take any other medicines.

Certain medicines, if given together with Pedea, may cause side effects. These are detailed below:

- your baby may have problems passing urine and may have been prescribed diuretics. Ibuprofen may reduce the effect of these medicines.

- your baby may be given anticoagulants (medicine preventing blood clotting). Ibuprofen may increase the anti-clotting effect of this product.

- your baby may be given nitric oxide to improve blood oxygenation. Ibuprofen may increase the risk of bleeding.

- your baby may be given corticosteroids to prevent inflammation. Ibuprofen may increase the risk of bleeding in the stomach and intestines.

- your baby may be given aminosides (one family of antibiotics) to treat infection. Ibuprofen may increase blood concentrations and thus increase the risk of toxicity on kidney and ear

Pedea contains sodium
This medicinal product contains less than 1 mmol sodium (15 mg) per 2 ml, i.e. essentially 'sodium-free'.

3. How to use pedea

Pedea will only be given to your baby in a special neonatal intensive care unit by qualified healthcare professional.

A course of therapy is defined as three intravenous injections of Pedea given at 24 hour intervals. The dose to be administered will be calculated from the weight of your baby. It is 10 mg/kg for the first administration and 5 mg/kg for the second and the third administrations.

This calculated amount will be given by infusion in a vein over a period of 15 minutes.
If after this first course of treatment, the *ductus arteriosus* is not closed or re-opens, your baby's doctor may decide to give a second course of treatment.

If after the second course of treatment, the *ductus arteriosus* is still not closed, a surgery may then be proposed.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. However, it is difficult to distinguish them from frequent complications occurring in premature babies and complications due to the disease.

The frequency of possible side effects listed below is defined using the following convention:
very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data)

Very common:
- Decrease in the number of platelets in the blood (thrombocytopenia),
- Decrease in white blood cells called neutrophils (neutropenia),
- Increase in creatinine level in the blood,
- Decrease in sodium level in the blood,
- Breathing problems (bronchopulmonary dysplasia),

Common:
- Bleeding inside the skull (intraventricular haemorrhage) and brain injury (periventricular leukomalacia),
- Bleeding in the lung,
- Perforation of the intestine and injury of intestinal tissue (necrotizing enterocolitis),
- Reduced volume of urine passed, blood in the urine, fluid retention

Uncommon:
- Acute failure of the kidney's functions
- Bleeding in the intestine
- Below normal oxygen content in the arterial blood (hypoxemia)

Not known:
- Perforation of the stomach
- 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). Stop using Pedea if you develop these symptoms and seek medical attention immediately. See also section 2.
- Pedea, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your baby's kidneys and affect them removing acids properly from your baby's blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium

in your baby's blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Reporting of side effects
If your baby gets any side effects, talk to your baby's doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system :Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or AppleApp Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store pedea

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

After opening, Pedea should be administered immediately.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Pedea contains

- The active substance is ibuprofen. Each ml contains 5 mg ibuprofen. Each 2 ml ampoule contains 10 mg ibuprofen.
- The other ingredients are trometamol, sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid 25% (for pH adjustment) and water for injections.

What Pedea looks like and contents of the pack
Pedea 5mg/ml solution for injection is a clear, colourless to slightly yellow solution.
Pedea 5mg/ml solution for injection is supplied in cartons of four 2 ml ampoules.

Marketing Authorisation Holder
Recordati Rare Diseases
Tour Hekla
52, avenue du Général de Gaulle
F- 92800 Puteaux
France

Manufacturer

Recordati Rare Diseases
Tour Hekla
52, avenue du Général de Gaulle
F-92800 Puteaux
France

or

Recordati Rare Diseases
Eco River Parc
30, rue des Peupliers
F-92000 Nanterre
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

United Kingdom
Recordati Rare Diseases UK Ltd.
Tel: +44 (0)1491 414333

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The following information is intended for medical or healthcare professionals only:

As for all parenteral products, ampoules of Pedea should be visually inspected for particulate matter and the integrity of the container prior to use. Ampoules are intended for single use only, any unused portions must be discarded.

Posology and method of administration (see also section 3)

For intravenous use only. Treatment with Pedea can only be carried out in a neonatal intensive care unit under the supervision of an experienced neonatologist.
A course of therapy is defined as three intravenous doses of Pedea given at 24-hour intervals.
The ibuprofen dose is adjusted to the body weight as follows:
- 1st injection: 10 mg/kg,
- 2nd and 3rd injections: 5 mg/kg.

If the *ductus arteriosus* does not close 48 hours after the last injection or if it re-opens, a second course of 3 doses, as above, may be given.
If the condition is unchanged after the second course of therapy, surgery of the PDA may then be necessary.
If anuria or manifest oliguria occurs after the first or second dose, the next dose should be withheld until urine output returns to normal levels.

Method of administration:
Pedea should be administered as a short infusion over 15 minutes, preferably undiluted. To facilitate the administration an infusion pump may be used.
If necessary, the injection volume may be adjusted with either sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection. Any unused portion of the solution should be discarded.
The total volume of solution injected to preterm infants should take into account the total daily fluid volume administered. A maximal volume of 80 ml/kg/day on the first day of life should usually be respected; this should be progressively increased in the following 1-2 weeks (about 20 ml/kg birthweight/day) up to a maximal volume of 180 ml/kg birthweight/day.

Incompatibilities

Chlorhexidine must not be used to disinfect the neck of the ampoule as it is not compatible with the Pedea solution. Therefore, for asepsis of the ampoule before use, ethanol 60% or isopropyl alcohol 70% is recommended.
When disinfecting the neck of the ampoule with an antiseptic, to avoid any interaction with the Pedea solution, the ampoule must be completely dry before it is opened.

This medicinal product must not be mixed with other medicinal products except sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution.

In order to avoid any substantial variation of pH due to the presence of acidic medicinal products that could remain in the infusion line, the latter must be rinsed before and after administration of Pedea with 1.5 to 2 ml of either sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution.