EMEA/H/C/000549

EPAR summary for the public

Pedea

ibuprofen

This is a summary of the European public assessment report (EPAR) for Pedea. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Pedea.

What is Pedea?

Pedea is a solution for injection that contains the active substance ibuprofen.

What is Pedea used for?

Pedea is used to treat 'patent ductus arteriosus' in newborn premature babies who were born six or more weeks too early (less than 34 weeks gestational age). Patent ductus arteriosus is a condition where the ductus arteriosus (the blood vessel that allows blood to bypass the baby's lungs before birth) fails to close after birth. This causes heart and lung problems in the baby.

The medicine can only be obtained with a prescription.

How is Pedea used?

Treatment with Pedea should only be carried out in a neonatal intensive care unit under the supervision of an experienced neonatologist (a doctor specialising in newborn babies).

Pedea is given as three injections into a vein at 24-hour intervals. Each injection lasts 15 minutes. The first injection is given when the baby is at least six hours old. If the ductus arteriosus has not closed by 48 hours after the final injection, or if it re-opens, a second course of three doses of Pedea may be given. If the condition is unchanged after the second course of therapy, surgery may be necessary.

Pedea should not be used before there is proof that the baby has patent ductus arteriosus.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How does Pedea work?

The active substance in Pedea, ibuprofen, has been used since the 1960s as a painkiller and an anti inflammatory medicine. It works by reducing the level of chemical messengers called prostaglandins within cells. As prostaglandins are also involved in keeping the ductus arteriosus open after birth, Pedea is thought to work by reducing the levels of prostaglandins, allowing this blood vessel to close.

How has Pedea been studied?

Because ibuprofen has been in use for a long time, the company presented information from the published literature. It also presented the results of studies, including one study looking at different doses of Pedea in 40 newborn premature babies. The main measure of effectiveness was the number of babies whose ductus arteriosus closed without the need for surgery.

A further study compared the effects of Pedea and placebo (a dummy treatment) in 131 newborns who were treated before there was proof that they had patent ductus arteriosus.

What benefit has Pedea shown during the studies?

In the study looking at the treatment of patent ductus arteriosus, the approved dose of Pedea led to a closure rate of 75% in babies born 11 to 13 weeks premature (six out of eight) and 33% in babies born 14 to 16 weeks premature (two out of six).

In study looking at the use of Pedea before there was proof that the babies had patent ductus arteriosus, Pedea seemed to be more effective than placebo at preventing surgery. However, the study had to be stopped early because of side effects (kidney and lung problems).

What is the risk associated with Pedea?

The cause of any side effects seen in babies receiving Pedea is difficult to assess because they may be related to the patent ductus arteriosus or to Pedea itself. The most common side effects seen in babies receiving the medicine (seen in more than 1 baby in 10) are thrombocytopenia (low blood platelet counts), neutropenia (low levels of neutrophils, a type of white blood cell), bronchopulmonary dysplasia (abnormal lung tissue, usually seen in babies born prematurely), increased blood creatinine levels (a marker of kidney function) and decreased blood sodium levels. For the full list of all side effects reported with Pedea, see the package leaflet.

Pedea must not be used in babies who have a life-threatening infection, bleeding, blood clotting problems or significant kidney problems. It must also not be used in babies with congenital heart disease where an open ductus arteriosus is needed for the blood to flow, or in babies with necrotising enterocolitis (a severe bacterial infection causing death of tissue in the gut). For the full list of restrictions see the see the package leaflet.

Why has Pedea been approved?

The CHMP decided that Pedea's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Pedea

The European Commission granted a marketing authorisation valid throughout the European Union to Orphan Europe SARL on 29 July 2004.

The full EPAR for Pedea can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Pedea, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.This summary was last updated in 11-2015.