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Ibuprofen Gen.Orph (*ibuprofen*)

An overview of Ibuprofen Gen.Orph and why it is authorised in the EU

What is Ibuprofen Gen.Orph and what is it used for?

Ibuprofen Gen.Orph is a medicine 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.

Ibuprofen Gen.Orph is a 'generic medicine'. This means that Ibuprofen Gen.Orph contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Ibuprofen Gen.Orph is Pedea. For more information on generic medicines, see the question-and-answer document here.

Ibuprofen Gen.Orph contains the active substance ibuprofen.

How is Ibuprofen Gen.Orph used?

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

Ibuprofen Gen.Orph 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 Ibuprofen Gen.Orph may be given. If the condition is unchanged after the second course of therapy, surgery may be necessary.

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

For more information about using Ibuprofen Gen.Orph, see the package leaflet or contact your doctor or pharmacist.

How does Ibuprofen Gen.Orph work?

The active substance in Ibuprofen Gen.Orph, 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

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after birth, Ibuprofen Gen.Orph is thought to work by reducing the levels of prostaglandins, allowing this blood vessel to close.

How has Ibuprofen Gen.Orph been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Pedea, and do not need to be repeated for Ibuprofen Gen.Orph.

As for every medicine, the company provided studies on the quality of Ibuprofen Gen.Orph. There was no need for 'bioequivalence' studies to investigate whether Ibuprofen Gen.Orph is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Ibuprofen Gen.Orph is given by injection into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Ibuprofen Gen.Orph?

Because Ibuprofen Gen.Orph is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Ibuprofen Gen.Orph authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Ibuprofen Gen.Orph has been shown to be comparable to Pedea. Therefore, the Agency's view was that, as for Pedea, the benefits of Ibuprofen Gen.Orph outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Ibuprofen Gen.Orph?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ibuprofen Gen.Orph have been included in the summary of product characteristics and the package leaflet.

Any additional measures in place for Pedea, such as a patient card with key safety information, also apply to Ibuprofen Gen.Orph where appropriate.

As for all medicines, data on the use of Ibuprofen Gen.Orph are continuously monitored. Suspected side effects reported with Ibuprofen Gen.Orph are carefully evaluated and any necessary action taken to protect patients.

Other information about Ibuprofen Gen.Orph

Ibuprofen Gen.Orph received a marketing authorisation valid throughout the EU on 16 February 2024.

Further information on Ibuprofen Gen.Orph can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ibuprofen-gen-orph. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 02-2024.