14 December 2023
EMA/CHMP/562650/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ibuprofen Gen.Orph

ibuprofen

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ibuprofen Gen.Orph, intended for the treatment of a haemodynamically significant patent ductus arteriosus (PDA) in preterm newborn infants of less than 34 weeks of gestational age. The applicant for this medicinal product is Gen.Orph.

Ibuprofen Gen.Orph will be available as a 5 mg/ml solution for injection. The active substance of Ibuprofen Gen.Orph is ibuprofen, a cardiac preparation (ATC code: C01EB16). Ibuprofen is a non-selective inhibitor of cyclo-oxygenase that reduces prostaglandin synthesis, which is believed to be the main mechanism of action in the closure of patent ductus arteriosus in preterm infants.

Ibuprofen Gen.Orph is a generic of Pedea, which has been authorised in the EU since 29 July 2004. Studies have demonstrated the satisfactory quality of Ibuprofen Gen.Orph. Since Ibuprofen Gen.Orph is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Pedea was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age.

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

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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