European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF NEGATIVE OPINION FOR ORPHAN DESIGNATION OF ibuprofen L-lysinate for the treatment of patent ductus arteriosus in premature neonates of less than 34 weeks of gestational age

On 21 September 2004, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of ibuprofen L-lysinate for the treatment of patent ductus arteriosus in premature neonates of less than 34 weeks of gestational age. A negative decision was granted by the European Commission on 24 June 2005.

The sponsor applied for orphan designation on the basis of the severity and rarity of the condition, as well as an assumption of potential benefit despite currently available methods of treatment.
The negative opinion is based on the following elements:

- the sponsor has not established that patent ductus arteriosus in premature neonates of less than 34 weeks of gestational age (hereinafter referred to as "the condition") affects not more than 5 in 10,000 persons in the Community at the time the application was made*;

- satisfactory methods of treatment of the condition are available in the Community, and justification has not been provided that ibuprofen L-lysinate may be of significant benefit to those affected by the condition;

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

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*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 25), Norway, Iceland and Lichtenstein. This represents a population of 459,700,000 (Eurostat 2004). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

Patients' association contact point:

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