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 midazolam hydrochloride (for oromucosal use) for the treatment of seizures which continue for at least five minutes

On 30 July 2003, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of midazolam hydrochloride (for oromucosal use) for the treatment of seizures which continue for at least five minutes. A negative decision was granted by the European Commission on 1 March 2004.

The sponsor applied for orphan designation on the basis of 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 element:

The sponsor has not established that seizures which continue for at least five minutes affect not more than 5 in 10,000 persons in the Community at the time the application was made.*

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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Patients' association contact point: Not available

*Disclaimer: The number of patients affected by the condition is estimated and assessed for the purpose of the designation, for a European Community population of 385,000,000 (Eurostat 2002) and may differ from the true number of patients affected by the condition. This estimate is based on available information and calculations presented by the sponsor at the time of the application.