23 June 2011
EMA/CHMP/438483/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Buccolam

midazolam

On 23 June 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a PUMA, a paediatric use marketing authorisation for the medicinal product Buccolam, 2.5 mg/0.5 ml; 5 mg/1 ml; 7.5 mg/1.5 ml; 10 mg/2ml, oromucosal solution intended for treatment of acute seizures in children. The applicant for this medicinal product is ViroPharma SPRL. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Buccolam is midazolam, a benzodiazepine derivative. Midazolam has an anticonvulsant effect. It also exerts a sedative and sleep-inducing effect of pronounced intensity, and an anxiolytic and a muscle-relaxant effect.

The benefit with Buccolam is its ability to stop a prolonged, convulsive, seizure in a new dosage form developed for buccal use in children. The most common side effects are respiratory depression, sedation, somnolence, depressed levels of consciousness, nausea and vomiting.

A pharmacovigilance plan for Buccolam will be implemented as part of the marketing authorisation.

The approved indication is:

Treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years).

Buccolam must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

For infants between 3-6 months of age treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available.

[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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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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Buccolam and therefore recommends the granting of the PUMA, a paediatric use marketing authorisation.