28 April 2016
EMA/CHMP/244784/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Umbipro

chlorhexidine

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004[1] for the medicinal product Umbipro, intended for the prophylaxis of omphalitis (infection of the umbilical cord) in newborn infants. This medicinal product has been developed by GlaxoSmithKline Trading Services Ltd.

Umbipro will be available as a gel (4% w/w). The active substance of Umbipro is chlorhexidine, an antiseptic and disinfectant (ATC code: D08AC02) which is effective against a wide range of Gram-negative and Gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses.

The benefits with Umbipro are its ability to reduce overall mortality in newborn infants who are delivered in community or primary care centres in resource-limited settings. Known safety issues relating to the topical use of chlorhexidine products include skin irritation and systemic hypersensitivity reactions/anaphylaxis.

The full indication is: “Umbipro is indicated for prophylaxis of omphalitis (infection of the umbilical cord) in newborn infants”.

Detailed recommendations for the use of this medicinal product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR).

Umbipro is intended exclusively for markets outside the European Union.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

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