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EPAR summary for the public

Umbipro

Chlorhexidine digluconate

This is a summary of the European public assessment report (EPAR) for Umbipro. It explains how the Agency assessed the medicine to reach its recommendations on the conditions of use for Umbipro.

What is Umbipro and what is it used for?

Umbipro is an antiseptic gel used to prevent infections of the umbilical cord (omphalitis) in newborn babies.

Umbipro contains the active substance chlorhexidine.

How is Umbipro used?

Umbipro is intended for use in countries outside the EU, in communities where healthcare resources are limited. It is available as a gel (7.1%) in a sachet. The caregiver should apply one sachet to the stump and skin around the base of the umbilical cord once daily for seven days or according to local guidelines. For babies born before 32 weeks of pregnancy, it should only be applied one time.

The first dose of Umbipro should be applied as soon as possible in the 24 hours after birth. For further information, see the package leaflet.

The medicine can be obtained without a prescription.

How does Umbipro work?

The active substance in Umbipro, chlorhexidine, is an antiseptic agent commonly used as a mouthwash for gum infections and as a cream or solution to prevent skin infections. It works by attaching to and disrupting the membrane around the microbial cells thereby killing them or preventing their growth.

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What benefits of Umbipro have been shown in studies?

Data from several published studies in Nepal, Bangladesh and Pakistan show that application of a chlorhexidine solution to the umbilical cord of newborn babies substantially reduces mortality (by between 20% and 38%) in babies delivered in community or primary care centres, where resources are limited. The studies also showed a reduction in umbilical cord infection, ranging from 24% to 75%, when chlorhexidine was used. Because Umbipro is a gel and not a solution, the company also presented studies to show that Umbipro and chlorhexidine solution produce similar reductions in the number of bacteria on the skin, and kill bacteria at a similar rate.

What are the risks associated with Umbipro?

The currently marketed chlorhexidine formulations (antibacterial solution, cream and mouthwash) have occasionally given rise to allergic reactions and to skin reactions. In rare cases, allergic reactions have been severe.

Umbipro must not be given by caregivers known to have had allergic reactions to chlorhexidine. For the full list of all side effects and restrictions with Umbipro, see the package leaflet.

Why has Umbipro received a positive scientific opinion?

In countries outside the EU and in settings with limited resources, the application of chlorhexidine solution to the umbilical cord area has contributed to reducing overall mortality. Regarding safety, data from studies and extensive post-marketing experience with currently available products suggest that skin reactions and serious allergies are very rare. Since Umbipro has been shown to be similar to chlorhexidine solution, the Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Umbipro's benefits are greater than its risks and granted a positive scientific opinion.

What measures are being taken to ensure the safe and effective use of Umbipro?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Umbipro have been included in the summary of product characteristics and the package leaflet.

Other information about Umbipro

The CHMP gave a positive scientific opinion on Umbipro on 28 April 2016. This opinion was given as part of the EMA's cooperation with the World Health Organisation, whereby the CHMP provides opinions on medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

The full EPAR for Umbipro can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Umbipro, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.