EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 January 2014
EMA/CHMP/750274/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1]

Hemoprostol

misoprostol

On 23 January 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive scientific opinion in accordance with Article 58 of Regulation (EC) No 726/2004, for the medicinal product Hemoprostol, 200 µg, tablet, intended for the treatment of Post Partum Haemorrhage due to uterine atony in situations where intravenous oxytocin is not available.

The scientific opinion holder for this medicinal product is Linepharma France. It may request a re-examination of this CHMP opinion, provided it notifies the European Medicines Agency in writing of its intention within 15 days of receipt of the opinion.

The active substance of Hemoprostol is misoprostol, a prostaglandin (ATC Code: G02AD06) and its mode of action is by inducing contractions of the smooth muscle fibers in the myometrium.

The benefits with Hemoprostol are its ability to reduce post partum bleeding due to uterine atony (although in a lesser extent than oxytocin), and thus may offer a treatment option in situations where intravenous oxytocin is not available. The most common side effects are shivering, fever, nausea (very common).

The approved indication is: "Hemoprostol is indicated in women of childbearing age for treatment of Post Partum Haemorrhage due to uterine atony in situations where intravenous oxytocin is not available."

The recommended posology for treatment of post partum hemorrhage is four tablets (800 micrograms) to be taken in a single sublingual intake.

The CHMP recommends Hemoprostol to be subject to medical prescription. It is ultimately the responsibility of the National Regulatory Authorities to decide on the adequate supply status.

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).

[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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Hemoprostol.

This medicinal product Hemoprostol (200 µg, tablet) is exclusively intended for markets outside the European Union.