EMA/51137/2014
EMEA/H/W/002652

EPAR summary for the public

Hemoprostol

misoprostol

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

What is Hemoprostol and what is it used for?

Hemoprostol is a medicine that contains the active substance misoprostol. It is used to treat women with post-partum haemorrhage (serious bleeding in the 24 hours after giving birth). Hemoprostol is used when the haemorrhage is due to failure of the muscles of the womb to contract (uterine atony) and when the usual treatment, injection or infusion (drip) into a vein of a medicine called oxytocin, is not available or where it is not feasible to give oxytocin because there are no facilities to give medicines into a vein.

How is Hemoprostol used?

Hemoprostol is given as a single dose of four sublingual tablets (tablets to be placed beneath the tongue) each containing 200 micrograms of misoprostol. The tablets are placed under the tongue and allowed to melt for 20 minutes.

For further information, see the package leaflet.

How does Hemoprostol work?

The active substance in Hemoprostol, misoprostol, is a synthetic medicine that acts like a substance naturally produced in the body, prostaglandin E_1. It acts on muscles, including the muscles of the womb, to make them contract (tighten). After childbirth, the muscles of the womb normally contract firmly, sealing off the blood vessels that supply the womb. If this fails to happen properly the blood vessels may continue to bleed, causing serious blood loss (post-partum haemorrhage). By stimulating the muscles of the womb to contract as they should, Hemoprostol can control post-partum haemorrhage and reduce the loss of blood.

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What benefits of Hemoprostol have been shown in studies?

Hemoprostol has been shown to be of benefit in one main published study, involving 978 women who developed post-partum haemorrhage and had not been given a medicine during labour that would help prevent bleeding. Treatment with Hemoprostol was compared with an infusion of oxytocin and the main measures of effectiveness were that bleeding stopped within 20 minutes, and that less than 300 ml of further blood loss occurred after the treatment had been given. The study found that 90% of women given Hemoprostol (440 of 488 women) and 96% of those given oxytocin (468 of 490) had their bleeding controlled within 20 minutes; 70% of Hemoprostol-treated and 83% of oxytocin-treated women did not lose more than 300 ml of blood after treatment.

The company originally presented the results of a study intended to show that Hemoprostol was also useful in preventing post-partum haemorrhage from developing in the first place, but as the study failed to show benefit the company withdrew its application for this use during the assessment.

What are the risks associated with Hemoprostol?

The most common side effects with Hemoprostol (which may affect more than 1 in 10 people) are nausea (feeling sick), and shivering and fever which generally occur within 60 to 90 minutes after the medicine is given and are usually short-lived. For the full list of all side effects reported with Hemoprostol, see the package leaflet.

Hemoprostol must not be given to patients who are hypersensitive (allergic) to the medicine or any of its ingredients, nor to those who are allergic to other medicines of the same class (prostaglandins). It must also not be given to pregnant women and therefore may not be used before the birth of the baby.

Why has Hemoprostol received a positive scientific opinion?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that although less effective than oxytocin, Hemoprostol had been shown to be of benefit in the treatment of women with post-partum haemorrhage. It could therefore be assumed that it may be beneficial in situations where oxytocin is not available or where it is not feasible to give oxytocin because there are no facilities to give medicines into a vein. The safety of the medicine was considered acceptable provided the measures recommended in the product information and risk management plan were followed and that its use was adequately regulated in order to avoid any misuse. The Committee therefore considered the benefits of Hemoprostol in the treatment of post-partum haemorrhage due to uterine atony are greater than its risks and granted a positive scientific opinion.

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

A risk management plan has been developed to ensure that Hemoprostol is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Hemoprostol, including the appropriate precautions to be followed by healthcare professionals and patients. Further information can be found in the summary of the risk management plan.

Other information about Hemoprostol

The CHMP gave a positive scientific opinion on Hemoprostol on 23 January 2014. 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 and risk management plan summary for Hemoprostol can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Medicines for use outside the EU. For more information about treatment with Hemoprostol, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2014.