

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hemocane Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride Ph Eur	0.65	% w/w
Zinc Oxide Ph Eur	10.0	% w/w
Bismuth Oxide	2.0	% w/w
Cinnamic Acid BP	0.45	% w/w
Benzoic Acid Ph Eur	0.4	% w/w

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Effective treatment for the symptoms of haemorrhoids and allied ano-rectal conditions.

4.2 Posology and method of administration

Adults – apply morning and night and after bowel movements until the

condition are controlled. Not recommended for children.

Cream is inserted into the rectum (via an applicator) and/or externally in the anal region.

4.3 Contraindications

Not to be used in those with a known history of allergy toward lidocaine and any of other components of the product actives and ingredients.

4.4 Special warnings and precautions for use

If symptoms persist or worsen, or if an allergic reaction occurs, discontinue use immediately and consult your doctor. Persons who suffer from haemorrhoids are advised to consult their doctor. Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

Lidocaine has been in wide spread use for many years. No specific effects on the reproductive process have been reported. However caution should be exercised when used in pregnancy. Lidocaine crosses the placental barriers. It is excreted in breast milk in small amounts.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

In rare cases, lidocaine has been associated with allergic reactions, including anaphylactic reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdose is unlikely to occur, if Hemocane cream is used as per the SPC. However, Overdose is very rarely reported. At worst, CNS (convulsion, irritability, somnolence) and cardiovascular effects (ventricular tachycardia) have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lidocaine has local anaesthetic properties. Zinc oxide and bismuth oxide, when applied locally, have mild astringent actions and provide a soothing, protective action on mucous membranes and raw surfaces.

5.2 Pharmacokinetic properties

Lidocaine is readily absorbed from the mucous membranes and through damaged skin. Intravenous data shows plasma concentrations to decline rapidly with a half-life of about 10 minutes. The elimination half-life is about 2 hours and excretion is through the kidneys. These effects are considered to have a minimal effect from the application of HEMOCANE Cream. Zinc oxide and bismuth oxide are insoluble in water and are not absorbed in any appreciable amount.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other ingredients: Propylene Glycol Ph Eur, Glycerol Ph Eur, Cetostearyl Alcohol B.P. Polawax EM3354, Arlacel 83, Polysorbate 80 B.P.

6.2 Incompatibilities

None

6.3 Shelf life

Three Years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

25 and 45 g aluminium tubes in a cardboard carton together with a pile pipe.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 43217/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th January 2005

10 DATE OF REVISION OF THE TEXT

03/08/2022