

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Hemoplus® Cream

(Chlorhexidine 25mg, Hydrocortisone and 10mg and

Gentamicin 3.5mg)

1. NAME OF THE MEDICINAL PRODUCT

Hemoplus® (Chlorhexidine 25mg, Hydrocortisone and 10mg and Gentamicin 3.5mg) Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Hemoplus® cream contains 25mg Chlorhexidine, 10mg Hydrocortisone and 3.5mg Gentamicin

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

Hemoplus® cream is indicated for internal and External Hemorrhoids (Piles), Perianal Eczema and Anal Fissures

4.2 Posology and method of administration

Posology

Cream

HEMORRHOIDS are clusters of vascular tissue, smooth muscle, and connective tissue arranged in 3 columns along the anal canal. They are present in healthy individuals as cushions that help to maintain continence. Although hemorrhoids are normal structures, the term hemorrhoid has come to refer to a pathologic or symptomatic process.

TYPES

There are two types of hemorrhoids:

1. Internal—above the dentate line, and
2. External—below the dentate line.

Internal hemorrhoids are supported within the anal canal by connective tissue. When this supporting tissue is weakened by straining or ageing, hemorrhoids may prolapse (i.e. distend so that they are pushed outside the anus). They may or may not bleed, and they rarely cause thrombosis. External hemorrhoids are prone to thrombosis, and when they disappear and heal, marisca (skin tags) frequently occur.

FOR EXTERNAL USE

1. Squeeze the tube of Hemoplus®cream and apply a small amount to your finger
2. Apply the Hemoplus® cream around the outside of your anus with your finger
3. Use Hemoplus®cream 2-3times during the day including before bed and first thing in the morning.
4. Wash your hand thoroughly with warm water and soap after each application of Hemoplus®cream.

FOR INTERNAL USE

1. Try to have a bowel movement before an internal application of Hemoplus®cream.
2. Attach the included round-tip applicator to the tube of Hemoplus®cream.
3. Squeeze the tube of hemoplus cream gently to fill the applicator
4. Lubricate the end of the applicator with petroleum jelly or another lubricant.
5. Gently insert the rounded tip of the applicator into your rectum.
6. Squeeze the tube of Hemoplus®gently to move the cream in the applicator into the rectum. Be careful not to squeeze too hard.
7. Remove the applicator and wash with soap and warm water.
8. Wash your hands with soap and water
9. Try not to have a bowel movement for at least two hours after an internal application of Hemoplus®cream.

Method of Administration

For Topical administration (Internal and External)

4.3 Contraindications

Hypersensitivity to gentamicin, corticosteroids and other ingredients of the formulation.

Long term use should also be avoided.

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

KEEP OUT OF THE REACH OF CHILDREN!

4.6 Fertility, pregnancy and lactation

Dyschezia (constipation) has been proved to put pregnant women at risk of hemorrhoidal thrombosis(1).Pressure from the enlarging uterus starting Increase in blood flow in the pelvic area, can cause the veins of the rectal wall to swell, itch and bulge. Treatment for these patients needs to be chosen carefully to avoid risks associated with pregnancy.Although data confirming the efficacy of local topical agents in hemorrhoidal thrombosis is scarce, they are widely prescribed. As their action is exclusively local, they can be prescribed without risk at any stage of pregnancy and during breast-feeding. Lastly, the management of such women presenting with pain should also include mainly Paracetamol-based analgesics, which are risk-free at the usual dosage (2)

4.7 Effects on ability to drive and use machines

None identified

4.8 Undesirable effects

None Identified

4.9 Overdose

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: , ATC code:

Pharmacotherapeutic group:

Mechanism of Action

Chlorhexidine in Hemoplus® is a broad spectrum antiseptic agent with persistent activity on the skin. It is nonirritating, active in the presence of body fluids, and has rapid bactericidal activity. It disrupts microbial cell membranes and coagulates cytoplasmic proteins.

Chlorhexidine has a residual activity of several hours. It is nonirritant, nontoxic and works in organic debris. As an antiseptic, it reduces bacteria introduced from faecal leakage and as an astringent; it causes coagulation of proteins in the cells of the perianal skin or the lining of the anal canal. This action promotes dryness of the skin, which in turn helps relieve burning, itching and pain.

Hydrocortisone-The anti-inflammatory, anti-pruritic, anti-allergic, anti-proliferative, vasoconstrictive and anti-exudative effects of hydrocortisone ameliorate the inflammation, vasodilatation, bleeding, and oozing associated with hemorrhoids, thereby supporting the healing process and eventually resulting in relief from

symptoms of pain, itching and pressure. As the mechanism of action of corticosteroids is via the expression and suppression of cellular proteins, symptomatic relief is delayed.

Gentamicin- This is a broad spectrum bactericidal antibiotic. Its mechanism of action involves inhibition of bacterial protein synthesis by binding to 30S ribosomes. Gentamicin is indicated for acute serious infections, such as those caused by gram-negative bacteria of fecal origin

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

Non-clinical data reveal no special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels 10 times higher than those achieved with clinical doses.

6. Pharmaceutical particulars

6.1 List of excipients

Liquid Parafin
Stearic Acid
Ceto- Stearyl Alcohol
Cetomacrogol
Propylene Glycol
Benzyl Alcohol
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30 °C. Protect from light and moisture.

6.5 Nature and contents of container

Hemoplus[®] cream is presented as a White homogeneous cream packed in a 20g Aluminum tube in a folding box board with leaflet enclosed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0 Applicant/Manufacturer

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