SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

PYLOOCAIN OINTMENT (Anti-Haemorrhoidal Ointment), 30gm

2. Qualitative and quantitative composition

Each gram contains
Betamethasone Valerate BP 0.5 mg
Phenylephrine Hydrochloride BP 1 mg
Lidocaine Hydrochloride BP 25 mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

PYLOOCAIN OINTMENT (Anti-Haemorrhoidal Ointment) is effective medicine for providing fast and effective relief from pain and bleeding associated with

- Anal fissures
- Haemorrhoids
- After Haemorroidectomy
- Mild Proctitis

4.2 Posology and method of administration

Apply two or three a day, use the applicator for deep anal administration Pyloocain Ointment can be applied before and after defecation. Or as directed by the physician.

4.3 Contraindications

Hypersensitivity to any ingredient.

4.4 Special warnings and precautions for use

Patients are instructed to consult with their physician if they experience severe or troublesome adverse reaction, they become pregnant or intend to become pregnant or they have any other question.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions are not likely to occur.

4.6. Fertility, pregnancy and lactation

None

4.7 Effects on ability to drive and use machines

None Known

4.8 Undesirable effects

Mild burning, stinging, itching or redness.

4.9 Overdose

If irritation develops, use of ointment should be discontinued and appropriate therapy instituted.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Betamethasone valerate

Betamethasone valerate is a glucocorticoid. Betamethasone as the valerate salt is used here topically on the skin and its effects are limited to the local anti-inflammatory activity. Betamethasone has both local anti-inflammatory and immunosuppressive activity. Thus Betamethasone inhibits the adherence of neutrophils and monocyte-macrophages to the capillary endothelial cells of the inflamed area. The drug blocks the effect of macrophage migration inhibitory factor and decreases the activation of plasminogen to plasmin. Finally, by inhibition of phospholipase A2 activity, via formation of lipocortin, Betamethasone reduces the formation of prostaglandins and leukotrienes in local tissue.

Phenylephrine hydrochloride

Phenylephrine hydrochloride is a sympathomimetic amine with a predominantly direct alpha-adrenergic action.

Lidocaine hydrochloride

If substantial quantities of local anesthetics are absorbed through the mucosa, actions on the central nervous system (CNS) may cause CNS stimulation and/or CNS depression. Actions on the cardiovascular system may cause depression of cardiac conduction and excitability and, with some of these agents, peripheral vasodilation.

5.2 Pharmacokinetic properties

Pharmacokinetic properties
Betamethasone valerate

Betamethasone 17-valerate is absorbed through the skin in varying proportions of the applied dose depending upon the severity of the damage to the stratum corneum barrier that has resulted from the skin disease. It is probable that no more than 5% of the applied dose is absorbed; it is metabolized in the liver and excreted by the renal tract. The remainder will be washed off or deposited on clothes or dressings. Under plastic occlusion a much higher proportion will be absorbed due to the increased temperature and humidity.

Phenylephrine Hydrochloride :
Phenylephrine hydrochloride is a sympathomimetic amine with a predominantly direct alpha-adrenergic action. It works by temporarily narrowing the blood vessels in the area. This effect decreases swelling and discomfort.

Lidocaine hydrochloride

Absorption
Lidocaine is readily absorbed through mucous membranes into the systemic circulation. The rate of absorption is influenced by the vascularity or rate of blood flow at the site of application, the total dosage (concentration and volume) administered, and the duration of exposure. Absorption from mucous membranes of the throat or respiratory tract may be especially rapid. Addition of a vasoconstrictor to the anesthetic may not reduce or slow absorption sufficiently to protect against systemic effects.
Protein binding:
Lidocaine—Concentration-dependent, to alpha 1-acid glycoprotein; usually about 60 to 80% at concentrations of 1 to 4 mcg per mL (4.3 to 17.2 micromoles per L).

5.3 Preclinical safety data
No particular toxicity reported.

6. Pharmaceutical particulars
6.1 List of excipients

White soft paraffin BP

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

- Store at a temperature below 30ºC.

6.5 Nature and contents of container

20g & 30g tube with cannula in a carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Galentic Pharma (India) Pvt. Ltd.

Samruddhi Venture Park, 4th Floor,
MIDC Central Road, Andheri (East),
Mumbai 400 093.
Telephone no: + 91 22 2838 2233/+91 224221 2400
E-mail address: sangani@galentic.com/ info@galentic.com

8 DOSIMETRY (IF APPLICABLE) :

Not Applicable

9 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE): Not Applicable