

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

PYL-X OINTMENT

Hydrocortisone Acetate, Lidocaine, Zinc Oxide & Allantoin Ointment

2. Qualitative and quantitative composition

Hydrocortisone Acetate BP 0.25% w/w

Lidocaine USP.....3.0 % w/w

Zinc oxide USP 5.0 % w/w

Allantoin BP 0.5 % w/w

Excipients Q.S

3. Pharmaceutical form

Ointment

A white to off-white Ointment.

4. Clinical particulars

Therapeutic indications

PYL-X OINTMENT is used in treatment of painful hemorrhoids, anal fissures and anal itch.

Posology and method of administration

Route of administration: Cutaneous route.

Apply **PYL - X OINTMENT** twice or thrice a day before or after defecation or as directed by physician.

For topical administration.

Contraindications

PYL - X OINTMENT is contraindicated in patients with allergy or hypersensitivity to hydrocortisone, lidocaine, allantoin, zinc oxide or to any of the ingredients of the product and in the presence of viral or bacterial infections unless an alternative treatment is given.

Special warnings and precautions for use

PYL - X OINTMENT can be used in children below 12 years only under medical supervision. Use of ointment during pregnancy or lactation can be done only under medical supervision if benefits are found to outweigh the risk.

Interaction with other medicinal products and other forms of interaction

Oral intake of the ingredients of **PYL - X OINTMENT** are shown to interact with drugs like barbiturates, carbamazepine, phenytoin, thioamides, anticholinestrase, anticoagulant and non-depolarizing muscle relaxant. Caution should be taken while using **PYL - X OINTMENT** along with above listed drugs.

Pregnancy and lactation

The safety of this product in pregnancy and lactation has not been established, but is not thought to constitute a hazard, though caution should be exercised during the first trimester.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

Certain reactions observed locally at the site of action are rash, hives, itching, rectal pain, burning, skin atrophy with the use of **PYL – X OINTMENT**.

Overdose

In view of the nature of the presentation of this product, accidental or deliberate overdosage is highly unlikely. In the event of overdosage, this will initially produce excessive anaesthesia of the upper gastrointestinal tract. Treatment of potential overdosage should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Topical anti haemorrhoidal.

ATC code: C05A X

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. Lidocaine has a local anaesthetic action, which relieves pain and discomfort in the affected areas. Zinc oxide applied externally has a mild astringent action on the skin. Allantoin is claimed to promote healing.

Pharmacokinetic properties:

The onset of action of lidocaine is 3-5 minutes on mucous membranes. Lidocaine can be absorbed following application to mucous membranes with metabolism taking place in the liver. Metabolites and unchanged drug are excreted in the urine.

Absorption of hydrocortisone may occur from normal intact skin and mucous membranes. Corticosteroids are metabolised mainly in the liver but also in the kidney, and are excreted in the urine.

Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

List of excipients

Microcrystalline wax BP

Light liquid Paraffin BP

White soft paraffin BP

Incompatibilities

Not applicable.

Shelf life

24 months.

Special precautions for storage

Store in a cool and dry place, below 30°C.

Nature and contents of container

Lami Tubes of 30 gm packed in a inner carton along with leaflet.

Special precautions for disposal

No special requirements.

7. Marketing authorisation holder:

Kremoint Pharma Pvt. Ltd.,
B-8 Additional MIDC, Ambernath
Ambernath (E). Thane 421506

8. Marketing authorisation number(s):

Registration Number: 04746/06687/NMR/2018

9. Date of first authorisation/renewal of the authorisation

Approval Date: 19.11.2019

10. Date of revision of the text:

Revision of Text : 19.11.2024