CALMOSEPTINE® OINTMENT PACKAGE INSERT

1. NAME OF THE MEDICINAL PRODUCT

Calmoseptine Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1) Menthol 0.44%
2) Zinc Oxide 20.6 %

3. PHARMACEUTICAL FORM

Not Applicable

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Calmoseptine Ointment is indicated in adults and children aged 12 years and above. For neonates, infants and children under 12 years of age: consult a physician.

4.2 Posology and method of administration

Posology

The efficacy of Calmoseptine Ointment in children aged 12 years and under has been established.

Method of administration

Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently pat dry or air dry before application of this product. Apply externally to the affected area up to 6 times daily or after each bowel movement.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. Certain persons can develop allergic reactions to ingredients in this product. Certain people may be sensitive to the menthol strength; however, it is typically tolerated.

4.4 Special warnings and precautions for use

1) For External Use Only.
2) Keep out of reach of children.
3) Avoid contact with eyes.
4) Do not put this product in the rectum.
5) Do not exceed the recommended daily dosage unless directed by a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy

The use of Calmoseptine Ointment may be considered during pregnancy, if necessary.

Breast-feeding

Calmoseptine Ointment can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Calmoseptine Ointment has no influence on the ability to drive and use machines.

4.8 Undesirable effects

1) Could cause burning sensation to patients with sensitivity to Menthol.
2) Stop use and ask a doctor if:
    i. condition worsens or does not improve within 7 days
    ii. bleeding occurs
    iii. symptom being treated does not subside
    iv. if redness, irritation, swelling, pain or other symptoms develop
    v. an allergic reaction develops

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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.

4.9 Overdose

In case of accidental ingestion contact a Poison Control Center immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Phamacodynamics properties

Pharmacotherapeutic group: not yet assigned

5.2 Pharmacokinetic properties

Absorption

The active ingredients exert their therapeutic effect without being absorbed into the systemic circulation.

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorothymol, Glycerin, Lanolin, Petrolatum, Phenol, Sodium Bicarbonate, and Thymol in a suitable ointment base

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

Five (5) years from the date of manufacture

6.4 Special precautions for storage

Store between 15-30°C (59-86°F)

6.5 Nature and contents of container

Ointment, available packaging - 3.5g Sachets

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6.6 Special precautions for disposal

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Zuellig Pharma Ltd Thailand, 8-9th Floor Ploenchit Center, 2 Sukhumvit Road, Klongtoey, Bangkok 10110. Thailand**.**

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8. MARKETING AUTHORISATION NUMBER

2C XXXXX/64

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: DD Month YYYY
Date of latest renewal: DD Month YYYY

10. DATE OF REVISION OF THE TEXT

07 January 2021

11. DOSIMETRY

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not Applicable