PROFESSIONAL INFORMATION

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1. NAME OF THE MEDICINE

ESKAMEL ACNE AND PIMPLE OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains:

Resorcinol 2 g and

Sulphur 8 g in a stable grease-free flesh-tinted vehicle.

Preservative:

Nipastat 0,25 % *m/m*

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eskamel Acne and Pimple Ointment is a smooth, brown, non-greasy ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Eskamel Acne and Pimple Ointment is indicated in the treatment of pimples, blemishes and acne.

4.2 Posology and method of administration

Adults and Children

Wash the affected areas with soap and water and dry carefully. Apply Eskamel Acne and Pimple Ointment thinly to the skin with the fingers but do not rub in. Once a day is

usually enough, but if the patient has a very oily skin, the ointment may be applied more often. Eskamel Acne and Pimple Ointment may be used under make-up to mask the spots and lesions of acne.

4.3 Contraindications

Do not use in patients who are sensitive to sulphur or resorcinol.

4.4 Special warnings and precautions for use

Use with care on acutely inflamed areas or near the eyes.

FOR EXTERNAL USE ONLY.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. It is unlikely that treatment with Eskamel Acne and Pimple Ointment will have any effect on the ability to drive and use machines.

4.8 Undesirable effects

Moderate erythema and scaling are the expected effects of Eskamel Acne and Pimple Ointment. If these are excessive or if inflammation occurs, stop treatment until the reaction has subsided and then apply Eskamel Acne and Pimple Ointment at longer

intervals. Resorcinol may be absorbed through the skin or from ulcerated surfaces and prolonged use may lead to myxoedema due to the antithyroid action of resorcinol. Central Nervous System stimulation and convulsions may occur as a result of systemic absorption.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See "Side-effects and Special Precautions". Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.11 Acne Preparations.

Eskamel Acne and Pimple Ointment has mild antiseptic, keratolytic and exfoliative properties.

5.2 Pharmacokinetic properties

Eskamel Acne and Pimple Ointment is for topical administration. No absorption studies have been carried out.

5.3 Preclinical safety data

Eskamel Acne and Pimple Ointment contains well-known active substances.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol 96 % *v/v*

Titanium dioxide CI no.: 77891

Chocolate Brown HT CI no.: 20285

Propylene glycol

Lily of the Valley fragrance

Potassium hydroxide

Bentonite

Purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25°C in a dry place. Keep in the original specially-lined tubes to prevent evaporation. KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Printed laminate tubes fitted with white linerless plastic caps, filled to 20 g, 40 g, 50 g or 100 g. Not all pack sizes may be available.

6.6 Special precautions for disposal

None.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

G1370 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

25 September 1974

10 DATE OF REVISION OF THE TEXT

20 October 2019