

Dosage form and strength: Each 50 g Ointment contains Precipitated Sulphur 2,63 g

1.5.5.1 Clean Proposed Professional information

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Intlaahlaa No. 1 Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 50 g contains:

Precipitated sulphur 2,63 g

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Ointment

A smooth yellow ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Intlaahlaa No.1 ointment is used for the treatment of pimples, ringworms and superficial fungal infections.

4.2 Posology and method of administration

FOR EXTERNAL USE ONLY.

First wash the affected area with warm water, then apply the ointment vigorously, morning and night.

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4.3 Contraindications

- Hypersensitivity to the active substance, sulphur, or any of the other ingredients of **Intlaahlaa No. 1** ointment.

4.4 Special warnings and precautions for use

FOR EXTERNAL USE ONLY.

Contact with the eyes, mouth and other mucous membranes should be avoided.

Wash hands immediately after use. Discontinue use if irritation develops.

Application of **Intlaahlaa No. 1** ointment to open wounds or to damaged or burned skin is not recommended.

4.5 Interaction with other medicines and other forms of interaction

Intlaahlaa No.1 ointment may interact with topical mercurial products that can lead to the generation of hydrogen sulfide, which has a foul odour and may stain the skin black.

Intlaahlaa No.1 ointment can discolour certain metals such as silver.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

No fertility data is available.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Frequency unknown: Skin irritation, dermatitis.

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4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity.

Refer to section 4.8.

Treatment of accidental ingestion is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatological preparations.

ATC code: D11A

Sulphur is a keratolytic, a mild antiseptic, a mild antifungal and a parasiticide.

5.2 Pharmacokinetic properties

No data is available for the proposed formulation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Rose oil

White petroleum jelly

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a well-closed container at or below 25 °C.

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6.5 Nature and contents of container

Intlaahlaa No. 1 is packaged in 50 ml natural PVC and polypropylene round jars with white snap-on caps in packs of 50 g.

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION:

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8. REGISTRATION NUMBER

G2003 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION

N/A as this is an old medicine

10. DATE OF REVISION OF THE TEXT

31 October 2024