

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