

Product Name: **KRISHAT SULFUR OINTMENT**

Generic Name: **Sulfur Ointment USP**

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### **1.3 Product Information**

#### **1.3.1 Summary of Product Characteristics (SmPC):**

**1. NAME OF THE MEDICINAL PRODUCT:**

KRISHAT SULFUR OINTMENT (Sulfur Ointment USP)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Composition:

Precipitated sulphur USP 10 % W/W

Petroleum base Q.S.

**3. PHARMACEUTICAL FORM: TOPICAL OINTMENT**

**4. CLINICAL PARTICULARS:**

**4.1 Therapeutic Indications**

Krishat sulphur ointment is used in the treatment of scabies, seborrheic dermatitis, And ache vulgaris.

It is also used in the treatment of other chronic skin conditions like psoriasis, ringworm and lupus erythematosus.

**4.2 Posology and Method of Administration**

Adults, children over 12 years and the elderly

*Mild dandruff*

To be used intermittently as an adjunctive treatment to be applied approximately once a week.

*Psoriasis, eczema, seborrhoeic dermatitis and severe dandruff*

To be used daily for three to seven days until improvement has been achieved.

Intermittent

repeated applications may be necessary to maintain improvement.

In all cases, the affected area should be treated and shampooed off using warm water approximately one hour later.

Children 6-12 years

To be used under medical supervision only.

Children under 6 years

Not recommended.

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#### **4.3 Contraindications**

The product is contraindicated in patients known to be sensitive to any of the ingredients including sulphur and salicylates, in the presence of acute local infections, or acute pustular psoriasis.

#### **4.4 Special warnings and precautions for use**

Do not use if the tube membrane is already perforated. Do not use on inflamed or broken skin.

Avoid contact with mouth, mucous membranes and eyes and wash hands immediately after use. Discontinue use if irritation develops.

If symptoms persist after four weeks, a doctor should be consulted.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None

#### **4.6 Fertility, pregnancy and lactation**

If possible it should not be used during pregnancy or lactation. However, inadvertent, accidental exposure is not cause for clinical intervention. There is no sufficient clinical experience to establish the safety of sulphur in general during pregnancy and lactation. It is unknown whether sulphur crosses the placenta or is excreted in breast milk.

#### **4.7 Effects on ability to drive and use machines**

None

#### **4.8 Undesirable effects**

Bronchospasm has been reported very rarely in patients with either pre-existing asthma or a family history of hypersensitivity to salicylates.

#### **4.9 Overdose**

Overdose is extremely unlikely. Treat symptomatically, if necessary.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

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**Pharmacotherapeutic group:** Antiacne

**ATC Code:**D10AB

**Mechanism of Action:**

Sulphur is a keratolytic, with weak antiseptic and parasiticide properties.

### **5.2 Pharmacokinetic properties**

No data is available for the proposed formulation.

### **5.3 Preclinical safety data**

Not applicable

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Mineral oil USP

White ointment USP

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Store at a temperature not exceeding 25°C.

### **6.5 Nature and contents of container**

The gel is filled into lami tube and packed in inner carton along with leaflet. Pack sizes available is 30g.

### **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7. Marketing authorisation holder**

**Kremoint Pharma Pvt. Ltd.,**

B-8 Additional MIDC, Ambernath,

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**8. Marketing authorisation number(s)**

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**9. Date of first authorisation/renewal of the authorisation**

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**10. Date of revision of the text**

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