Product Name: KRISHAT SULFUR OINTMENT

Generic Name: Sulfur Ointment USP

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 erythematous.

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.

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

Product Name: KRISHAT SULFUR OINTMENT

Generic Name: Sulfur Ointment USP

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.

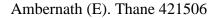
7. Marketing authorisation holder

Kremoint Pharma Pvt. Ltd.,

B-8 Additional MIDC, Ambernath,

Product Name: KRISHAT SULFUR OINTMENT

Generic Name: Sulfur Ointment USP



8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text
