

1. NAME OF THE MEDICINAL PRODUCT

Sulphur Skin Ointment
Precipitated Sulphur

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Sulphur skin ointment contains 100mg of Precipitated Sulphur

Excipients:

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

Sulphur skin 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**Posology**

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, seborrheic 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

Mode of Administration(s): Topical

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 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

No Reported case

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

Pharmacotherapeutic group: Antiacne,
ATC code: D10AB

Systemic as well as topical application of iodides can activate the metabolism and occasionally counteract the cloudiness of the vitreous body. The effect of iodine on early senile cataracts has not yet been established. Occasionally it is possible to slow down the progression of cloudiness and the degradation of visual acuity.

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

Liquid Paraffin
White soft paraffin.

6.2 Incompatibilities

None known

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30⁰C, and protect from light and moisture.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Smooth pale yellow ointment contained in 25g sulphur skin ointment tube.

6.6 Special precautions for disposal <and other handling>

No special requirements

7. SUPPLIER

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8. DATE OF REVISION OF THE TEXT

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