

1. NAME OF THE DRUG PRODUCT

PRODUCT NAME: Sulphur 10%

BRAND NAME: Sulfacan Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Sulphur10%

Excipients.....q.s

For complete list of excipients refer section 6.1.

3. PHARMACEUTICALS FORM:

Ointment

Pale yellow smooth homogenous ointment and very smooth when applied to the skin

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Sulfacan ointment is used in the treatment of scabies, seborrheic dermatitis, and acne 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:

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, 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

Product Name: Sulfacan Ointment (Sulphur 10%)

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 warning 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 Drug Interactions

None

4.6 Pregnancy & 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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Overdose is extremely unlikely. Treat symptomatically, if necessary

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

ATC Code: D10AB

Product Name: Sulfacan Ointment (Sulphur 10%)

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

Anhydrous lanoline, Cetostearyl alcohol, Hard paraffin, Micro crystalline wax, Chlorocresol, Liquid paraffin, Fragrance (rose crystal)

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Store in a cool dry place

6.5 Nature and contents of container

The ointment 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. APPLICANT

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:

Plot 6, New Makun City,
Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu.
Ogun State,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 6, New Makun City,

Product Name: Sulfacan Ointment (Sulphur 10%)

Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu.
Ogun State,
NIGERIA

8. WHO PREQUALIFICATION REFERENCE NUMBER-

Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION-

Not applicable

10. DATE OF REVISION OF THE TEXT-

Not applicable