

**SUMMARY OF PRODUCT
CHARACTERISTICS (SmPC)**

**PRODUCT NAME
HYSULF OINTMENT
(SULFUR OINTMENT USP)**

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SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

HYSULF OINTMENT

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2. Qualitative and quantitative composition

Composition:

Precipitated Sulfur USP.....10.00 % w/w

Ointment Base Q.S

Batch Size: 575kg

Sr. No.	Ingredients	Specification	Label claim	Overages added (In %)	Quantity / 1gm (mg)	Quantity / 30gm Tube(mg)	Quantity of Batch in Kg
1.	Precipitated Sulfur	USP	10.00 %w/w	-	10.00	300.00	57.50
2.	Light Liquid Paraffin	BP	12.00 %w/w	-	12.00	360.00	69.00 Kg (82.14 Ltrs)
3.	White Bees Wax	BP	4.00%w/w	-	4.000	120.00	23.00
4.	White Soft Paraffin	BP	74.00 %w/w	-	74.00	2220.0	425.50

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Sulfur ointment may be used for the treatment of acne (pimples) and scabies (galis-aso).

4.2 Posology and method of administration

Posology

For Acne, skin Itch, Athlete's foot, Eczema like rash, foot itch:

Wash affected areas with a mild cleanser and water. Apply a thin layer of Sulfur ointment to pimple areas 1 to 3 times daily, or as directed by a physician. Avoid applying to normal skin to prevent excessive dryness. Wash hands after each application.

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Infection normally resistant to antifungal agents 4-6 weeks.

For Scabies:

Take a thorough bath before each application and 24 hours after the last treatment.

Apply Sulfur ointment and gently massage on all skin areas from the neck to the toes (including soles of the feet). Leave on for 24 hours after application. Repeat for 2 to 3 consecutive days, or as directed by a physician. All clothing and bedding used by a patient with scabies should be washed (using hot water) to avoid re-infestation or transmission of scabies.

To prevent the spread of scabies, everyone in the household or group, whether itching or not, should be treated at the same time.

Method of administration

Topical administration only.

4.3 Contraindications

To prevent excessive dryness and skin irritation, Sulfur products should not be used with other topical acne medications, unless directed by a physician.

4.4 Special warnings and precautions for use

FOR EXTERNAL USE ONLY

If you are allergic to any component of the product. In children younger than 2 years old, unless directed by a physician.

Avoid contact with the eyes, mouth and other mucous membranes. If the ointment comes in contact with the eyes, rinse out promptly and thoroughly with water.

4.5 Interaction with other medicinal products and other forms of interaction

HYSULF as a topical ointment does not interact with any other product.

4.6 Pregnancy and lactation

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.

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4.7 Effects on ability to drive and use machines

HYSULF ointment has no influence on the ability to drive and use machines.

4.8 Undesirable effects

In general, topical Sulfur is well tolerated when used as directed. Undesirable effects are most likely to occur when Sulfur is applied to broken skin and/or for a longer period of time. The following undesirable effects have been observed after using topical Sulfur: Local irritation of the skin, eyes or respiratory tract, Skin inflammation (which maybe severe), Clogging of pores producing, blackheads or whiteheads, Rare cases of allergic reactions, Systemic toxicity and several deaths after topical use of Sulfur 10% ointment for 3 days on babies with scabies, Sulfur stains clothing, bedding, and metal (e.g., silver and copper), including jewellery.

4.9 Overdose

Overdose is extremely unlikely. Treat symptomatically, if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Keratolytic, Antifungal, and Antibacterial

Pharmacotherapeutic classification:

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

Sulfur is converted to hydrogen sulfide (H₂S) through reduction, partly by bacteria. H₂S has a lethal action on bacteria (possibly including *Propionibacterium acnes*) which plays a role in acne, fungi, and parasites such as scabies mites.

Sulfur acts as a keratolytic agent and also it has antibacterial activity. It also kills fungi, scabies mites and other parasites.

5.2 Pharmacokinetic properties

No data is available for the proposed formulation.

5.3 Preclinical safety data

Not Known.

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6. Pharmaceutical particulars

6.1 List of excipients

Light Liquid Paraffin

White soft Paraffin

White Bees Wax

a. Incompatibilities

None known

b. Shelf life

3 years

c. Special precautions for storage

Store in a well closed container and avoid prolonged exposure to excessive heat.

d. Nature and contents of container

30 g pack of Lami Tube. Packed in Carton along with Leaflet.

e. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Name and address of Manufacturing Site:

GOPALDAS VISRAM & COMPANY LIMITED

Plot No. : A / 590-591, T.T.C. Industrial Area, M.I.D.C.,

Mahape, Navi Mumbai – 400 710, India.

Telephone : 91-22-41111710 / 717

E-Mail: sangeetajagani@gopaldasvisram.com

8. Marketing Authority

SUITELIFE PHARM LTD.

4, Ayo, Davies Close, Off Ekololu Street,

Surulere, Lagos State, Nigeria.