SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) FOR DRUG PRODUCTS IN NIGERIA

1. NAME OF THE DRUG PRODUCT

Brand Name: SULPHOREC
Generic Name: Sulfur Ointment USP

Strength:

Precipitated Sulfur USP……..10.0% w/w

Dosage form: Semi Solid Cream

Rout of administration: Topical

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label claim:

Precipitated Sulfur USP…….10.0% w/w

Mineral Oil USP…….10.0% w/w

White Ointment USP……..80.0% w/w

Batch Size: 1000 Kg

Sr. No	Ingredients	Specification	Qty/Batch in kg	Function
1	Precipitated Sulfur	USP	102.678 kg	Active
2	Light Liquid Paraffin	USP	100.00 kg	Emollient
3	White Soft Paraffin	USP	800.00 kg	Softening Agent
Total			1002.678 Kg	

3. PHARMACEUTICAL FORM

Semi Solid Cream

Yellow coloured smooth ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Precipitated form of sulphur is use in the treatment of scabies. The scabicidal effect is Probably due to its conversation into hydrogen sulphide and parathionic acid. In addition to its use in scabies, sulphur is also employed in the treatment of other chronic skin conditions like psoriasis, seborrhoea, ringworm and lupus erythematosus. Sulphur ointment contains 10 percent (2.5% in children) of sulphur in a simple ointment base. The ointment is to be rubbed on the affected area of the skin.

4.2 Posology/Dosage and method of administration:

Posology

Adults (including elderly/hepatically impaired) and children

As directed by Physician.

Method of administration

For topical administration.

A small quantity of Sulfur ointment should be applied to cover the affected area.

Any product remaining at the end of treatment should be discarded.

Do not mix with other preparations as there is a risk of dilution, resulting in a and potential loss of stability of the ointment.

4.3 Contraindication:

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.

It may stain fabrics and jewellery.

4.5 Interaction with other drug products and other forms of interaction

No drug interactions have been identified

4.6 Fertility, pregnancy and lactation

Sulfur topical has not been formally assigned to a pregnancy category by the FDA. Animal studies have not been conducted. There are no controlled data in human pregnancy. Sulfur topical should only be given during pregnancy when benefits outweigh risks.

4.7 Effects on ability to drive and use machines

No adverse effects on the ability to drive or operate machinery have been identified.

4.8 UNDESIRABLE EFFECTS

Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:

Very rare: Systemic allergic reactions including anaphylaxis, 29 authorization rash.

Skin and subcutaneous tissue disorders:

Common: Burning to the area of application.

Uncommon: Itching, erythema, stinging and dryness 29uthoriza to the area of application.

Cutaneous 29 uthorization reactions.

4.8 Overdose

Symptoms and signs

There is currently limited experience with overdosage of Sulfur Ointment.

Treatment

There is no specific treatment for an overdose of Sulfur Ointment. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D10AB02

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. Precipitated sulfur and colloidal sulfur are used, in form of lotions, creams, powders, soaps, and bath additives, for the treatment of acne vulgaris, acne rosacea, and seborrhoeic dermatitis.

5.2 Pharmacokinetic properties

Intended for local use only, no systemic absorption.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Ingredients	Specification
White Soft Paraffin	BP
Light Liquid Paraffin	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

1 X 30 GM Printed Aluminium tube in carton along with pack insert..

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

None

7.0 APPLICATION HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION:

M/S. GOLDMOORE INTERNATIONAL LTD.,
56, Olorublogbon Street, Anthony Village,
Lagos, Nigeria.

8.0 MANUFACTURED BY:

YASH MEDICARE PVT LTD.
Nr. Sabar Dairy, Talad Road,
Po. Hajipur, Tal. Himatnagar – 383 006,
Gujarat, India.

9. NAFDAC REGISTRATION NUMBER(S): 04-5175