1. NAME OF THE MEDICINAL PRODUCT

APHASULF OINTMENT
(SULPHUR OINTMENT USP 10 % w/w)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. N	Name of Raw Material	Reference	Quantity/ Batch In kg	Quantity in g / 30 g	Function
	Active				
1	Precipitated sulfur	USP	66.000	3.00	Active
	Excipients:				
2	Mineral oil	USP	66.000	3.00	Excipient (ointment base)
3	White Wax	USP	27.720	1.260	Excipient (ointment base)
4	White Petrolatum	USP	500.284	22.740	Excipient (ointment base)
	Total		**660.004=660**	**30.0**	

3. PHARMACEUTICAL FORM

Ointment (Topical Use)

Description: Light Yellow Coloured Homogenous ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aphasulf ointment is indicated as an aid in the treatment of Acne vulgaris. It is indicated for the treatment of seborrheic dermatitis. It is also indicated for the treatment of scabies, especially in infants under two months of age and in pregnant and nursing women.

4.2 Posology and method of administration

Used for seborrheic dermatitis:
Wash the affected area gently with soap & warm water. Dry with clean cloth. Apply ointment on the affected part of the body

Used for scabies:

Before applying: Wash entire body with soap and water; dry thoroughly, apply enough at bedtime to cover entire body from neck down; rub in gently; leave on body for 24 hours; wash entire body before applying again

Importance of washing entire body thoroughly 24 hours after the last treatment

Proper dosing: Missed dose: Using as soon as possible; not using if almost time for next dose.

Usual adult and adolescent dose: Anti-seborrheic

Keratolytic (topical): Topical, to the skin, one or two times a day.

Scabicide: Topical, to the entire body from the neck down, at bedtime for 3 nights; patients may bathe before each application and should bathe 24 hours following the last application.

Note: Treatment may be repeated after 1 week if there is no clinical improvement; additional weekly treatments should be administered only if there are live mites.

4.3 Contraindications

Aphasulf ointment is contraindicated in patients hypersensitive to sulfur or any other ingredients of this product.

4.4 Special warnings and precautions for use

Should be used with caution and under medical supervision.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations containing any of the following medications, depending on the amount present, may also interact with this medication. Abrasive or medicated soaps or cleansers or Acne preparations or preparations containing a peeling agent, such as Benzoyl peroxide, esorcinol, Salicylic acid, Tretinoin or, Acne preparations, topical, other or Alcohol-containing preparations, topical, such as After-shave lotions Astringents, Perfumed toiletries, Shaving creams or lotions or, Cosmetics or soaps with a strong drying effect or Isotretinoin or Medicated cosmetics or ``cover-ups" (concurrent use with sulfur may cause a cumulative irritant or drying effect, especially with the application of peeling, desquamating, or abrasive agents, resulting in excessive irritation of the skin).

4.6 Pregnancy and lactation:

Should be used with caution and under medical supervision in pregnancy and lactation

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects:

Redness of skin, itchy rash, mild burning sensation may be observed in some patients.

4.9 Overdose

An overdose of sulfur topical is unlikely to occur. If you do suspect an overdose, or if sulfur topical has been ingested, call a poison control center or emergency room for advice.

Apply the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed and apply only your next regularly scheduled dose.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Sulfur ointment has germicidal, fungicidal, parasiticidal and keratolytic properties. Its germicidal activity may be the result of its conversion to pentathionic acid by epidermal cells or by certain microorganisms.

5.2 Pharmacokinetic properties

Not applicable for topical preparations.

5.3 Preclinical Safety data

There are no pre-clinical data of relevance available.

6. Pharmaceutical particulars

6.1 List of excipients

Mineral oil	USP
White Wax	USP
White Petrolatum	USP

6.2 Incompatibilities

Not applicable

6.3. Shelf life

60 Months

6.4 Special precautions for storage

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

6.5. Nature and contents of container

12x30 g collapsible tube

One 30 gm collapsible tube packed in carton with leaflet and such 12 carton packed in one outer carton.

6.6. Special Precaution for Disposal

No special requirements

7. Applicant of Manufacturer.

NAFDAC Reg. No. B4-3349

MAXHEAL PHARMACEUTICALS (INDIA) LTD
J-7, M.I.D.C., TARAPUR INDUSTRIAL AREA,
BOISAR-401506, DIST. PALGHAR, INDIA.