

**1.3.1**  
**Summary Of Product Characteristics (SPC)**

---

### **1.3.1 Product information for health professionals**

#### **1.3.1.1 Invented Name of the Medicinal Product**

**AQUASULF**

(Sulfur Ointment USP)

#### **1.3.1.2 Strength**

Precipitated Sulfur USP.....10 % w/w

Mineral Oil USP.....10 % w/w

White Ointment USP.....80 % w/w

#### **1.3.1.3 Dosage Form**

Semisolid Dosage Form

#### **1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Precipitated Sulfur USP.....10 % w/w

Mineral Oil USP.....10 % w/w

White Ointment USP.....80 % w/w

#### **1.3.1.5 PHARMACEUTICAL FORM**

Ointment (Topical)

#### **1.3.1.6 CLINICAL PARTICULARS**

##### **1.3.1.6.1 Therapeutic indications**

Precipitated form of sulphur is use in the treatment of scabies. The scabicial 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.

---

#### **1.3.1.6.2 POSOLOGY 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.

#### **1.3.1.6.3 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.

#### **1.3.1.6.4 WARNING AND PRECAUTIONS**

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.

#### **1.3.1.6.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

No drug interactions have been identified.

#### **1.3.1.6.6 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.

---

#### **1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

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

#### **1.3.1.6.8 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.

#### **1.3.1.6.9 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.

#### **1.3.1.7 PHARMACOLOGICAL PROPERTIES**

##### **1.3.1.7.1 Pharmacodynamic Properties**

ATC Code: D10AB02

Sulfur is converted to hydrogen sulfide (H<sub>2</sub>S) through reduction, partly by bacteria. (H<sub>2</sub>S) 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.

**1.3.1.7.2 Pharmacokinetic properties**

Intended for local use only, no systemic absorption.

**1.3.1.7.2 Preclinical safety data**

None stated.

**1.3.1.8. PHARMACEUTICAL PARTICULARS**

**1.3.1.8.1 List of excipients**

Mineral Oil

White Ointment

**1.3.1.8.2 Incompatibilities:**

None stated.

**1.3.1.8.3 Shelf life:**

60 Months

**1.3.1.8.4 Special precautions for storage:**

Store below 30°C. Protect from Light.

**1.3.1.8.5 Nature and contents of container:**

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

**1.3.1.8.6 Special precautions for disposal and other Special handling:**

No special requirements

---

**1.3.1.9 Marketed by:**

**APHANTEE PHARMACEUTICAL NIGERIA LIMITED.**

Suit ff 11, First Floor,  
Pacific Complex no.9,  
Awka road, Onitsha,  
Anambra State, Nigeria

**1.3.1.10 Manufactured by:**

**YASH MEDICARE PVT LTD.**

Nr. Sabar Dairy,  
Talod Road, Po. Hajipur,  
Dist Himatnagar – 383 006,  
Gujarat, India.

---