

## SUMMARY OF PRODUCT CHARACTERISTICS.

### 1. Name of the medicinal product

Whitfield's Skin Ointment.

### 2. Qualitative and quantitative composition

Contains: Benzoic Acid 6.0%w/w and Salicylic Acid 3.0%w/w.

### 3.0 Pharmaceutical form: Ointment for topical application.

### 4.0 Clinical particulars

#### 4.1 Therapeutic indications

Whitfield's Ointment is recommended for the topical treatment of fungal infections of the skin.

#### 4.2 Posology and method of administration:

Topical administration (For external application only).

Whitfield Ointment is applied topically and is for external use only. Whitfield Ointment should be applied twice daily.

#### 4.3 Contraindications

Whitfield Ointment is contraindicated in patients with a known sensitivity to Benzoic Acid or Salicylic Acid.

#### 4.4 Special warnings and precautions for use

Whitfield's Antifungal 3% w/w & 6% w/w Ointment should not be used on skin affected by psoriasis or eczema. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Sodium laurylsulfate (E 487) may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area. Sensitivity to Sodium laurylsulfate (SLS) can vary according to body site, age and patient population (children, hydration level, skin color and disease). Patient populations with decreased skin barrier functions such as in atopic dermatitis are more sensitive to the irritant properties of SLS. Whitfield's Antifungal Ointment may cause allergic reactions in some patients. Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product. This preparation may make skin and surfaces slippery.

#### 4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with Whitfield Ointment

#### 4.6. Pregnancy and lactation

Whitfield Ointment should not be used in pregnancy without medical supervision

#### 4.7 Effects on ability to drive and use machines

No adverse effects reported.

#### 4.8 Undesirable effects

Side effects With Whitfield Ointment are very rare. Allergic reactions to Benzoic Acid have been reported. It can be irritant to the eyes, skin and mucous membranes. Salicylic Acid is a mild irritant, and application of preparations containing salicylic acid to the skin may cause dermatitis. Symptoms of acute salicylate poisoning have been reported after prolonged application of salicylic acid ointments to large areas of the body.

#### 4.9 Overdose.

No special procedures or antidote is likely to be necessary. Treatment is symptomatic and supportive.

### 5.0 Pharmacological properties

#### 5.1 Pharmacodynamic properties.

**Pharmacotherapeutic group:** Other antifungals for topical use.

**ATC code:** D01AE12.

#### **Pharmacology:**

Benzoic Acid has antibacterial and antifungal properties,

Salicylic Acid is bacteriostatic and fungicidal. It also possesses keratolytic properties.

#### 5.2 Pharmacokinetic properties

If systemic absorption occurs, benzoic acid is conjugated with glycine in the liver to form hippuric acid which is rapidly excreted in the urine. It may also be excreted as benzolglucuronic acid. Salicylic Acid is rapidly

distributed to all the body tissues if absorbed, and the rate of excretion in the urine is dependent on the pH.

**5.3 Preclinical safety data**

No additional data of relevance.

**6. Pharmaceutical particulars**

**6.1 List of excipients**

Petroleum Jelly, liquid paraffin and hard paraffin wax.

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

36 months from the date of manufacture. (3 years)

**6.4 Special precautions for storage**

Store in a dry place, below 30°C. Protect from light.

**6.5 Nature and contents of container**

20gm collapsible aluminium tubes in a unit box along with a literature insert.

**6.6 Special precautions for disposal and other handling**

None applicable.

**7. Marketing authorization holder/Registrant.**

Dawa limited

Plot No.7879/8, Baba Dogo Road, Ruaraka,

P.O Box 16633-00620, Nairobi –Kenya

**8. Manufacturer**

Dawa Limited

Plot No.7879/8, Baba Dogo Road, Ruaraka

P.O.BOX 16633-00620

Nairobi, Kenya.

Email:admin@dawalimited.com

**9. Date of revision of the text:**

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