

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

## **1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :**

**1.1 Brand Name : Whitfield's Ointment**

**1.2 Generic Name : Compound Benzoic Acid Ointment BP**

**1.3 Strength : Benzoic acid (6% w/w) + Salicylic Acid (3% w/w)**

**1.4 Pharmaceutical Form: Ointment**

## **2. QUALITATIVE & QUANTITATIVE COMPOSITION :**

Benzoic Acid BP 6% w/w

Salicylic Acid BP 3% w/w

Ointment base q.s.

## **3. PHARMACEUTICAL FORM**

Ointment

White or almost white translucent ointment

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Whitfield's Ointment is recommended for the topical treatment of fungal infections of the skin like Ringworm (tinea)

### **4.2 Posology and method of administration**

Skin Infections:

Apply a thin film of Whitfield's Ointment to the affected skin areas

Child: Apply twice daily.

Adult: Apply twice daily or as per direction of Physician.

#### **4.3 Contraindications**

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

#### **4.4 Special warnings and special precautions for use**

Avoid use of Whitfield's Ointment over broken or inflamed skin, avoid contact with eyes, and avoid contact with mucous membranes. Its use should be discontinued if excessive dryness or irritation of the skin occurs.

**Cautions, Further Information:** Salicylate toxicity may occur particularly if applied on large areas of skin.

#### **4.5 Interaction with other FPPs and Other forms of Interaction**

There are no known interactions; with Whitfield's Ointment.

#### **4.6 Pregnancy and lactation**

Whitfield's Ointment should not be used in pregnancy & lactation without medical supervision.

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

Not Known

#### **4.8 Undesirable effects**

Whitfield's Ointment may show hypersensitivity, skin burning sensation (mild) & skin reactions. However, side effects are very rare. Allergic reactions to Benzoic Acid have been reported. Salicylic Acid is mild irritant, may cause dermatitis.

#### **4.9 Overdose**

Overdose is unlikely, but in the event of accidental swallowing gastric irritation, nausea and vomiting may occur. Treatment is symptomatic and supportive.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties:**

##### **Benzoic Acid & Salicylic Acid**

**Pharmacotherapeutic group:** Antifungal & Keratolytic

**ATC Code:** D01AE12 other antifungals for topical use.

##### **Mechanism of action:**

Benzoic Acid helps to prevent infection caused by bacteria & fungi. Salicylic Acid helps the body to shed rough or dead skin cells. 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 benzoglucuronic 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

None Known

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

SN	Ingredients	Spec.
01.	Cetostearyl Alcohol	BP
02.	White Soft Paraffin (White Petroleum Jelly)	BP
03.	Liquid Paraffin (H)	BP

### 6.2 Incompatibilities

Not sufficient data available

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Do not Freeze. Protect from light. Keep Out of reach of Children. Store at a temperature not exceeding 30°C

### 6.5 Nature and contents of container

20g in an Aluminium barrier Laminate tube in an inner carton.

### 6.6 Instructions for use and handling

Please see the package insert.

## 7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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**8. MARKETING AUTHORISATION NUMBER**

**06878/08849/NMR/2021**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**Nov 28, 2021**

**10. DATE OF REVISION OF THE TEXT**

**01/01/2023**

