

**REGAL PHARMACEUTICALS LIMITED  
NAIROBI, KENYA**

**1.5.1 SUMMARY OF PRODUCT  
CHARACTERISTICS**

**APPLICATION FOR THE REGISTRATION OF WHITFIELD'S  
OINTMENT  
RWANDA FOOD AND DRUGS AUTHORITY**

## **1. Name of the medicinal product**

Whitfield's Ointment

## **2. Qualitative and quantitative composition**

Salicylic acid BP 3% w/w

Benzoic Acid BP 6% w/w

## **3. Pharmaceutical form**

Ointment.

White smooth mass of lanolin odour, free from visible impurities.

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

Whitfield's Antifungal 3% w/w & 6% w/w Ointment is recommended for the topical treatment of fungal infections of the skin.

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

Topical.

Adults, children and the elderly: apply twice daily to the affected area.

### **4.3 Contraindications**

Contraindicated in patients displaying salicylate hypersensitivity, or sensitivity to benzoic acid or any other ingredient in the preparation.

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

For external use only.

Whitfield's Ointment should not be used on skin affected by psoriasis or eczema.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Sodium lauryl sulfate 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 lauryl sulfate (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 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.

### **4.5 Interaction with other medicinal products 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 without medical supervision.

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

None likely.

#### **4.8 Undesirable effects**

Possible sensitivity reactions, drying and irritation.

#### **Reporting of suspected adverse reactions**

Side effects With Whitfield's Ointment are very rare.

**Benzoic Acid:** Allergic reactions to Benzoic Acid have been reported. It can be irritant to the eyes, skin and mucous membranes.

**Salicylic Acid:** 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

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

ATC Code D01AE12

Other antifungals for topical use.

**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 other information relevant to the prescriber other than that already stated in other sections of the SPC.

### **6. Pharmaceutical particulars**

#### **6.1 List of excipients**

White soft paraffin

Liquid Paraffin

Emulsifying wax (Anionic)

#### **6.2 Incompatibilities**

**Benzoic Acid** activity may be reduced in the presence of non-ionic surfactants.

#### **6.3 Shelf life**

36 months unopened.

#### **6.4 Special precautions for storage**

Store below 25°C.

**DECLARATION BY THE APPLICANT**

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partners States.

I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.

I also consent to the processing of information provided by the EAC Partner States.

It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules\*

Name: DR. DHARMESH BHAJI RASIK BHAJI PATEL  
Position in the company: COMPANY PHARMACIST

Signature: *[Handwritten Signature]* .....  
*Dr. Dharma Vohra*

Date: *3<sup>rd</sup> August 2020* .....  
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\* Note: If fees have been paid, attach proof of payment