

## **SUMMARY OF PRODUCT CHARACTERISTICS**

Penicillin Skin Ointment

## **1. NAME OF THE MEDICINAL PRODUCT**

Penicillin Skin Ointment

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each gram of the ointment contains Benzyl penicillin potassium 10,000 I.U

For a full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Semi-solid (Ointment)

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

Local treatment of topical infections of the skin, furunculi, burns, ulcers, infected wounds, abscess, impetigo, intertrigo, secondary infected eczema, as well as in the prevention of infections.

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

#### Posology

Apply in a thin layer to the affected area 2-3 times daily. Cover with a sterile dressing in order to avoid contamination of the affected area.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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

Do not use this medication if you are allergic to penicillin V or to any other penicillin antibiotic, such as amoxicillin (Amoxil), ampicillin (Omnipen, Principen), carbenicillin (Geocillin), dicloxacillin (Dycill, Dynapen), or oxacillin (Bactocill).

Before using penicillin V, tell your doctor if you are allergic to cephalosporins such as Ceclor, Ceftin, Duricef, Keflex, and others, or if you have asthma, kidney disease, a bleeding or blood clotting disorder, a history of diarrhea caused by taking antibiotics, or a history of any type of allergy.

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

Before taking penicillin V, tell your doctor if you are using any of the following drugs:

- Methotrexate (Rheumatrex, Trexall); or
- Probenecid (Benemid).

This list is not complete and there may be other drugs that can interact with penicillin V. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

### **4.6 Fertility, Pregnancy and Lactation**

It should only be prescribed in situations where the healthcare provider strongly believes that the benefit of its use largely outweighs any possible risks to the fetus and the pregnancy

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

Not Applicable

#### **4.8 Undesirable effects**

Penicillin Ointment applied in optimal amount is relatively well tolerated. Allergic reactions (exanthema, rash or urticaria) may occur at the site of application, but they will disappear after the cessation of the therapy.

#### **4.9 Overdose**

Not Applicable

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacological Properties**

Penicillin G and V are first generation penicillins that are used widely to treat infections due to susceptible organisms and have been linked rarely and only weakly with idiosyncratic liver injury.

#### **5.2 Pharmacokinetic properties**

The penicillins and their metabolites are potent immunogens because of their ability to combine with proteins and act as haptens for acute antibody-mediated reactions. The most frequent (about 95 percent) or "major" determinant of penicillin allergy is the penicilloyl determinant produced by opening the beta-lactam ring of the penicillin. This allows linkage of the penicillin to protein at the amide group. "Minor" determinants (less frequent) are the other metabolites formed, including native penicillin and penicilloic acids.

#### **5.3 Preclinical safety data**

Not Application

### **6. PHARMACEUTICAL PARTICULARS**

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

White Soft Paraffin

Liquid Paraffin

#### **6.2 Incompatibilities**

Not applicable

#### **6.3 Shelf life**

48 Months

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

Store below 30°C. Protect from light and moisture.

#### **6.5 Nature and contents of container and special equipment for use, administration or implantation**

Penicillin Skin Ointment is available in 20g tube with leaflet enclosed.

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

No special requirements.

### **7. APPLICANT/MANUFACTURER**

Drugfield Pharmaceuticals Limited  
Lynson Chemical Avenue Km38,  
Lagos-Abeokuta Expressway  
Sango-Otta, Ogun State, Nigeria  
Tel: +2348033513989  
Email:Info@drugfieldpharma.com