

**1. NAME OF THE MEDICINAL PRODUCT**

Gentamicin Skin Ointment (0.1% Gentamicin)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each gram of ointment contains 1.0mg of Gentamicin in the form of Gentamicin Sulphate

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Ointment

**4. CLINICAL PARTICULARS****4.1 Therapeutic indications**

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

**4.2 Posology and method of administration**

The ointment is to be applied to the affected part as prescribed by the practitioner. Apply 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 Gentamicin or any of its component.

**4.3 Special warnings and precautions for use**

Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs, or if irritation, sensitization, or superinfection develops, treatment with Gentamicin Sulfate Ointment USP, 0.1% should be discontinued and appropriate therapy instituted.

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

No interaction are known

**4.6 Pregnancy and lactation**

The product is topical preparation to be applied sparingly to the affected parts. The absorbed content has not been found to have such effects on the foetus.

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

None known

**4.8 Undesirable effects**

Localised side effects such as burning sensation, stinging and itching may be expected at the site of application. Nephrotoxicity and ototoxicity rarely occurs, if it occurs, the drug should be discontinued.

#### **4.9 Overdose**

There are no reports of overdosage of Gentamicin 0.1% cream

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Anti-biotic

ATC code: J01GB03

Gentamicin belongs to the group of aminoglycosides antibiotics that are derived from bacteria of the order Actinomycetales, micromonospora, e.t.c. The aminoglycosides have a similar antimicrobial action. They are bacteriocidal and act by interfering with bacterial protein synthesis, possibly by binding irreversibly to the 30s portion of the bacterial ribosomes. They are most active against gram-negative rods.

#### **5.2 Pharmacokinetic properties**

Gentamicin Sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. This product may clear infections that have not responded to other topical antibiotic agents. In impetigo contagiosa and other primary skin infections, treatment with a small amount of Gentamicin Sulfate Ointment three to four times daily usually clears the lesions promptly. In secondary skin infections, the product facilitates the treatment of the underlying dermatosis by controlling the infection. Bacteria susceptible to the action of Gentamicin Sulfate include sensitive strains of Streptococci (group A beta-hemolytic, alpha-hemolytic), Staphylococcus aureus (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria, Pseudomonas aeruginosa, Aerobacteraerogens, Escherichia coli, Proteus vulgaris and Klebsiellapneumoniae.

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

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

### **6. PHARMACEUTICAL PARTICULARS**

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

Gentamicin sulphate

Liquid paraffin (heavy)

White soft 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**

Gentamicin skin ointment is presented in a collapsible tube sealed with aluminium foil and covered with a screw cap

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

No special requirements

**7.0 Applicant/Manufacturer**

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

**8.0 DATE OF REVISION OF THE TEXT**

09/2022