

## Summary of product characteristic

### 1. Name of the medicinal product

Fidemycin skin Ointment BP

### 2. Qualitative and quantitative composition

Contains: Tetracycline hydrochloride BP 3.0% w/w

### 3. Pharmaceutical form

Ointment.

Yellow translucent non-gritty ointment free from any visible evidence of contamination.

### 4. Clinical particulars

#### 4.1 Therapeutic indications

Tetracycline is a bacteriostatic antibiotic with a wide spectrum of activity and has been used in the treatment of skin infections caused by susceptible organisms. It is used in the topical treatment of acne and rosacea.

Tetracycline may be of benefit in the treatment of melioidosis and infected animal bites.

#### 4.2 Posology and method of administration

Topical.

Clean and dry the affected area, apply the ointment to affected area by gentle massage once or twice daily or as directed by the physician.

#### 4.3 Contraindications

The ointment is contra-indicated in patients hypersensitive to any of this group of antibacterials, since cross - sensitivity may occur. It should not be used on broken or inflamed skin.

#### 4.4 Special warnings and precautions for use

For external use only.

Avoid contact with broken or inflamed skin.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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

There are no known interactions when used as indicated. No drug and substance interaction studies have been performed part of the clinical from the pharmacokinetic point of view.

#### 4.6 Pregnancy and lactation

Not to be used in pregnancy unless essential to the patient's welfare. Tetracyclines cross the placenta and may have toxic effects on foetal tissues, particularly on skeletal development,

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be appraised of the potential hazard to the foetus

Tetracyclines are also excreted in breast milk and therefore contraindicated in nursing mothers

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

None likely.

#### 4.8 Undesirable effects

Local allergic reactions like dermatitis have been reported.

#### 4.9 Overdose

Hypersensitivity reactions may occur. In case of such, patients are advice to stop using the product.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

Tetracycline is a short-acting antibiotic that inhibits bacterial growth by inhibiting translation.

It binds to the 30s ribosomal subunit and prevents the amino-acyl tRNA from binding to the A site of the ribosome.

It also binds to some extent to the 50S ribosomal subunit. This binding is reversible in nature. Additionally tetracycline may alter the cytoplasmic membrane of bacteria causing leakage of intracellular contents, such as nucleotides, from the cell.

### **5.2 Pharmacokinetic properties**

Bioavailability is less than 40% when administered via intramuscular injection, 100% intravenously, and 60- 80% orally (fasting adults). Food and/or milk reduce GI absorption of oral preparations of tetracycline by 50% or more. Its 20 - 67% protein bound. They are concentrated by the liver in the bile and excreted in the urine and feces at high concentrations in a biologically active form.

### **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.**

Hard paraffin

White soft paraffin

Liquid paraffin

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

36 months unopened.

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

Store in dry place, below 30°C. Protect from light. Keep all medicines out of reach of children.

### **6.5 Nature and contents of container**

Printed collapsible aluminium tube of 15grams packed in a unit box with literature insert.

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

No special requirements.

## **7.0 Marketing authorisation holder**

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.

## **9. Legal category: Prescription only medicine, (POM)**

## **10. Date of revision of the text:**

January 2019