

## PATIENT INFORMATION LEAFLET:

### BIOFULVIN TABLETS:

{GRISEOFULVIN 125 MG, 250 MG & 500 MG}.

*Read all of this leaflet carefully before you start using this medicine.*

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### ***In this leaflet:***

1. What BIOFULVIN is and what it is used for
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### **1. WHAT BIOFULVIN IS AND WHAT IT IS USED FOR**

The name of the medicine is Biofulvin. The active ingredient is Griseofulvin.

Griseofulvin belongs to a class of drugs called antifungals.

Griseofulvin oral tablet is used to treat fungal infections that can affect different parts of your body. These include your hair, nails, and skin. BIOFULVIN comes in three strengths:

Each tablet contains: Griseofulvin 125mg.  
Griseofulvin 250mg  
Griseofulvin 500mg.

### **2. BEFORE YOU USE BIOFULVIN**

#### **Do not use BIOFULVIN**

- If you are allergic (hypersensitive) to Griseofulvin or any of the other ingredients of the tablets.
  - if you suffer from porphyria.
  - if you suffer from Systemic Lupus Erythematosus (SLE).
  - if you have severe liver disease
  - if you are breastfeeding, pregnant or intend to get pregnant within 1 month (female) or 6 months (male) of stopping treatment.
- If any of the above applies to you, speak to your doctor or pharmacist.

#### **Take special care with BIOFULVIN**

Talk to your doctor or pharmacist before taking BIOFULVIN

- If you have liver or kidney problems

- If you are relying on oral contraceptives. You will need an additional barrier contraception, such as condoms during Griseofulvin therapy and for four weeks (female) and 6 months (male) after stopping the therapy.

#### **Taking/Using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor or pharmacist if you are taking: Ciclosporin, methadone, Oral contraceptives, sedatives and anticonvulsants.

#### **Taking BIOFULVIN with Food and Drink**

For the best effects, Griseofulvin should be taken after a high fat meal to enhance absorption

Avoid alcoholic drinks while you are taking Griseofulvin. Alcohol and Griseofulvin may cause a disulfiram reaction-you will feel sick, may be sick, blush, have an irregular heartbeat, and chest and / or abdominal pain.

#### **Pregnancy and breast-feeding**

Do not take BIOFULVIN if you are pregnant, planning to become pregnant or breast-feeding as they may harm the baby.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

#### **Driving and using machines**

Griseofulvin may cause drowsiness, dizziness, confusion, and lack of co-ordination. You should not drive or operate machinery until you are sure you are not affected.

### **3. HOW TO USE BIOFULVIN**

Always use BIOFULVIN exactly as your doctor or health care provider has told you. You should check with your doctor or pharmacist if you are not sure.

#### **For oral use**

*The usual adult dose:* 500 mg to 1000 mg a day, given as either a single dose, or as two equal doses.

*Children:* the dose depends on age and the weight, and is usually 10 mg / kilogram of body weight per day. The dose is usually given as two equal doses.

The length of time you have to take your medicine will be decided by your doctor. For ringworm infections of the hair or body, this could be 2-4 weeks, for infections of the scalp or feet it could be 4-8 weeks, and for infections of the nails, 6-12 months.

#### **If you use more BIOFULVIN than you should**

Tell your doctor, pharmacist, nurse or nearest hospital casualty department immediately.

Do this even if you feel well.

#### **If you forget to use BIOFULVIN**

If you forget to take a dose take it as soon as you remember.

Do not take a double dose to make up for a forgotten dose. Tell the doctor if you miss a dose

#### **If you stop using BIOFULVIN**

Do not stop just because you feel better. Keep taking your medicine until the prescribed course is finished.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

*Like all medicines, BIOFULVIN can cause side effects, although not everybody gets them.*

#### Seek immediate medical attention

Sore, painful, swollen skin, and joints, butterfly rash (attack of Systemic Lupus Erythematosus), severe skin reactions, including severe reddening of the skin, raised, itchy, painful skin rash. This may be an allergic reaction.

Common side effects: Headache, nausea and vomiting, stomach discomfort, dizziness, numbness, lower back pain, pale urine, yellowing of skin/eyes.

*If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

### **5. HOW TO STORE BIOFULVIN**

Do not store above 30°C. Store in a cool, dry place protected from direct sunlight

Keep out of the reach and sight of children.

Do not use BIOFULVIN after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

Do not use if you notice discolouration or any other physical signs of deterioration.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help to protect the environment

### **6. FURTHER INFORMATION**

#### **What BIOFULVIN contains**

The active substances in Biofulvin is Griseofulvin.

Biofulvin is available as follows:

**125mg tablets:** Round, flat-faced, bevel-edged, white tablets, scored on one side and plain on the other side.

**250mg tablets:** Round, flat-faced, bevel-edged, white tablets, scored on one side and plain on the other side.

**500mg tablets:** White coloured, round shaped, bevel edged tablets scored on one side and plain on the other side.

10 x 10's Blisters in unit box with a package insert.

Further information on summary of product characteristics can be obtained from the regulatory affairs department of Biodeal Laboratories Ltd. [regulatoryaffairs@biodealkenya.com](mailto:regulatoryaffairs@biodealkenya.com).

**This product should be used on the advice of a doctor or pharmacist.**



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