

PATIENT INFORMATION LEAFLET: BIOFULVIN 500MG TABLETS.

Read this leaflet carefully before you start taking this medicine.

- This medicine has been prescribed for your current medical problem only. It must not be given to other people or used for other problems unless you are otherwise directed by your doctor.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

In this leaflet:

1. What Biofulvin 500mg Tablets is and what it is used for
2. Before you use Biofulvin 500mg Tablets
3. How to use Biofulvin 500mg Tablets
4. Possible side effects
5. How to store Biofulvin 500mg Tablets
6. Further information

1. WHAT IS BIOFULVIN 500MG TABLETS AND WHAT IS IT USED FOR?

The name of the medicine Biofulvin 500mg Tablets which is an antifungal antibiotic that is active *in vivo* against common dermatophytes. The antifungal effect is manifested by binding to tubulin, at distinct binding sites, thus interfering with the microtubule function and causing inhibition of mitosis, and arresting cell division.

The inhibition of fungal mitosis leads to the production of multinucleate cells of characteristic morphology.

On entering the systemic circulation, griseofulvin binds to keratin in keratin precursor cells, thereby making them resistant to fungal infections. The drug only reaches the site of action when hair or skin is replaced by the keratin-griseofulvin complex.

Griseofulvin then enters the dermatophyte through energy dependent transport processes and binds to the fungal microtubules, interfering with, and inhibiting mitosis, and the deposition of fungal cell walls.

Each tablet contains:

Griseofulvin B.P 500mg.

2. BEFORE YOU USE BIOFULVIN 500MG TABLETS:

- Do not use Biofulvin 500mg Tablets without medical advice.
- Do not use Biofulvin 500mg Tablets if got hepatic impairment, systemic Lupus Erythematosus, Sexually active men and also women using contraceptives.

3. HOW TO USE BIOFULVIN 500MG TABLETS:

Biofulvin 500mg Tablets are taken orally. Tablets are swallowed whole with a glass of water and is recommended to be taken with a high fat meal, for increased absorption and minimizing GI distress.

4. POSSIBLE SIDE EFFECTS:

Like all medicines, Biofulvin 500mg Tablets can have side effects which include the following:

Blood and lymphatic system disorder, nervous system disorder, gastrointestinal disorders, Hepatobiliary disorders, Skin and subcutaneous tissue disorders.

5. HOW TO STORE BIOFULVIN 500MG TABLETS.

Do not use Biofulvin 500mg Tablets after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Biofulvin 500mg Tablets should be stored below 30°C in a cool dry place. Protect from direct sunlight.

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

6. FURTHER INFORMATION:

What Biofulvin 500mg Tablets contains:

The active substances in Griseofulvin B.P 500mg.

Biofulvin 500mg Tablets is a registered trademark of Biodeal Laboratories Ltd.

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com.

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

7. PRESENTATION:

Biofulvin 500mg Tablets is available as follows:

Tablets: 10 x 10 Blister packed Tablets with aluminum foil.



Manufactured by:
Biodeal Laboratories Ltd,
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