

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Finished Pharmaceutical Product

1.1 Strength

Each tablet contains:
Griseofluvin B.P. 500mg

Why is this medication prescribed?

Griseofulvin is used to treat skin infections such as jock itch, athlete's foot, and ringworm; and fungal infections of the scalp, fingernails, and toenails.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

How should this medicine be used?

Griseofulvin comes as a tablet, capsule, and liquid to take by mouth. It is usually taken once a day or can be taken two to four times a day. Although your symptoms may get better in a few days, you will have to take griseofulvin for a long time before the infection is completely gone. It is usually taken for 2 to 4 weeks for skin infections, 4 to 6 weeks for hair and scalp infections, 4 to 8 weeks for foot infections, 3 to 4 months for fingernail infections, and at least 6 months for toenail infections. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take griseofulvin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Shake the liquid well before each use to mix the medication evenly.

Continue to take griseofulvin even if you feel well. Do not stop taking griseofulvin without talking to your doctor.

What special precautions should I follow?

Before taking griseofulvin,

- tell your doctor and pharmacist if you are allergic to griseofulvin, or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially anticoagulants ('blood thinners') such as warfarin (Coumadin), oral contraceptives, cyclosporine (Neoral, Sandimmune), phenobarbital (Luminal), and vitamins.
- tell your doctor if you have or have ever had liver disease, porphyria, lupus, or a history of alcohol abuse.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking griseofulvin, call your doctor.
- tell your doctor if you drink alcohol.
- you should plan to avoid unnecessary or prolonged exposure to sunlight and to wear protective clothing, sunglasses, and sunscreen. Griseofulvin may make your skin sensitive to sunlight.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Griseofulvin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- upset stomach
- vomiting
- diarrhea or loose stools
- thirst
- fatigue
- dizziness
- faintness

If you experience any of the following symptoms, call your doctor immediately:

- fever
- sore throat
- skin rash
- mouth soreness or irritation

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Keep the liquid away from light. Do not freeze.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p>) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org>

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help>. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your response to griseofulvin.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription. If you still have symptoms of infection after you finish the griseofulvin, call your doctor.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

6.2 Incompatibilities

None reported

6.3 Shelf-Life

24 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light and moisture

6.5 Nature and Contents of Container

1 X 6 T Alu-Clear PVC Blister pack

6.6 Special Precautions for Disposal and other Handling

No special requirement.

7. Marketing Authorisation Holder and Manufacturing Site Addresses

GENEITH PHARMA. LIMITED

12, Adewale Crescent, Off Ewenla Street, Off Oshodi-Papa Exp. Way, Oshodi, Lagos, Nigeria.

8. Marketing Authorisation Number

9. Date of First Registration/Renewal of the Registration

10. Date of Revision of the Text

11. Dosimetry (If Applicable)

Not applicable

12. Instructions for Preparation of Radiopharmaceuticals (If Applicable)

Not applicable