

Package leaflet: Information for the user

Griseofulvin 125 mg and 500 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Griseofulvin Tablets are and what they are used for

Griseofulvin Tablets contain griseofulvin which is an antifungal antibiotic.

Griseofulvin kills the fungi that cause infections of:

- the skin, scalp, hair or nails.

It works by helping the newly formed skin, hair and nails to resist attack by fungi. As the new tissue grows, the old and infected is cast off. It is important to continue treatment until all the old infected tissue is gone.

2. What you need to know before you take Griseofulvin Tablets

Do not take Griseofulvin Tablets

- if you are allergic to griseofulvin or to any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or intending to become pregnant within 1 month of stopping treatment.
- if you are planning to father children within 6 months of treatment with these tablets.
- if you have severe liver disease.
- if you have porphyria (a metabolism disorder which causes abdominal pains and mental disorder).
- if you have systemic lupus erythematosus (a disorder which causes the immune system to attack the body).

Griseofulvin Tablets must **not** be taken if your skin, hair or nails are healthy, as a precaution to prevent a long-past infection returning.

If any of the above apply to you, speak to your doctor or pharmacist.

Other medicines and Griseofulvin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Griseofulvin Tablets or they may affect how well Griseofulvin Tablets will work.

Tell your doctor or pharmacist if you are taking:

- oral contraceptives (the pill). You will need an additional method of contraception, such as condoms while you are taking Griseofulvin Tablets and also during the month after stopping treatment
- phenylbutazone, a medicine used to treat a type of arthritis
- phenobarbitone, a medicine used to control epilepsy (fits)
- ciclosporin, a medicine used to suppress the immune system
- medicines that thin the blood (e.g. warfarin)
- any medicines that tend to make you sleepy, such as medication used to help you sleep or calm you down
- medicines containing alcohol. Griseofulvin Tablets may enhance the effect of alcohol.

Pregnancy and breast-feeding

DO NOT take Griseofulvin Tablets if you are pregnant or breast-feeding. Griseofulvin Tablets may cause birth defects and it may affect breast-fed babies.

If you become pregnant while taking Griseofulvin Tablets, stop taking them immediately and contact your doctor.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Important information for men and women:

- **Women** should avoid getting pregnant while taking Griseofulvin Tablets and up to one month after treatment.
- **Men** should not father children within six months of taking Griseofulvin Tablets.

Driving and using machines

Griseofulvin Tablets may cause tiredness or drowsiness. If this occurs do not drive, use machinery, or perform any tasks that may require you to be alert.

Protecting your skin

Griseofulvin Tablets may make your skin more sensitive to sunlight. Avoid direct sunlight and artificial UV light. When outside, wear protective clothing, hat and sunglasses, and use a sunblock that is at least SPF15 while taking Griseofulvin Tablets.

Griseofulvin Tablets contains propylene glycol

This medicine contains 0.268 mg propylene glycol in each 125 mg tablet and 1.55 mg propylene glycol in each 500 mg tablet.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Griseofulvin Tablets

Always take this medicine exactly as your doctor has told you and always read the label. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets whole with a drink of water. Take the tablets immediately after a meal.
- Griseofulvin may increase the effect of **alcohol**. Drinking alcohol with these tablets may cause fast heartbeat, flushing, increased sweating, or redness of the face. If you have this reaction or feel that the alcohol is affecting you more than usual, do not drink alcoholic drinks.

The recommended dose is

Adults: the usual dose is 500 mg to 1000 mg once daily. Your doctor may ask you to take a smaller dose several times a day.

Use in children: follow your doctor's instructions.

Keep taking the tablets for at least two weeks after all signs of infection have disappeared. You may need to take Griseofulvin every day for many weeks or months while new skin, hair or nails grow. This depends upon the thickness of keratin (hair, nails) at the site of infection.

- For toe or fingernails you may need 6 to 12 months treatment.
- For hair or skin at least 4 weeks treatment is required.

If you take more Griseofulvin Tablets than you should

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the container and any remaining tablets with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Griseofulvin Tablets

If you forget to take a dose, take it after food as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not use a double dose to make up for a forgotten dose.

If you stop taking Griseofulvin Tablets

Do not stop just because the infection seems to have cleared; the medicine may not have killed all the fungus. If you stop too soon, the infection may come back. Keep taking the tablets 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, this medicine can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

STOP taking the tablets and seek medical help immediately if you have any of the following **allergic reactions:**

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

Seek immediate medical attention if you have any of the following symptoms:

- yellowing of the skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away
- butterfly-shaped skin rash over the nose and cheeks made worse by exposure to the sun. Tiredness and joint pains.

Tell your doctor if you get any of the following side effects:

- reactions to the sun. Your skin may become red, painful and swollen – do not sunbathe, use a sun bed, or expose your skin to artificial UV light
- feeling confused, dizzy or unsteady
- feeling tired, drowsy or sleepy
- feeling of numbness and tingling in hands and feet
- griseofulvin may upset normal sperm production. Men wishing to father children within six months of treatment should discuss the possible side effects with their doctor.

The following side effects usually settle without changing the dose:

- diarrhoea and stomach problems
- nausea and vomiting

- headache.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Griseofulvin Tablets

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original container.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Griseofulvin Tablets contains

- The active substance is griseofulvin. Each tablet contains either 125 mg or 500 mg griseofulvin.
- The other ingredients are:
sodium laurilsulfate, povidone, maize starch, potato starch, microcrystalline cellulose, magnesium stearate and purified water.

The film coating contains:

hypromellose, ethylcellulose, acetylated monoglyceride, polysorbate 80, propylene glycol (E 1520), methylene chloride and isopropyl alcohol. (See end of Section 2 for further information on propylene glycol).

The tablets do not contain any flavouring or colouring agents.

What Griseofulvin Tablets look like and contents of the pack

- Griseofulvin 125 mg Tablets are off-white film-coated tablets, marked 'GF' on one side and '125' on reverse.
- Griseofulvin 500 mg Tablets are off-white film-coated tablets, marked 'GF' on one side and '500' on reverse.

They are available in containers of 100 tablets.

Marketing Authorisation Holder

Chemidex Pharma Ltd., trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.

Manufacturer

Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, the Netherlands.

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