

MODULE 1: ADMINISTRATIVE AND PRESCRIBING INFORMATION

MODULE 1.3 PRESCRIBING INFORMATION

Module 1.3.1 SmPC, Labelling, Leaflet

1.3.1.3 Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

Griseofulvin 500mg Film-coated Tablets

Griseofulvin

Read all of this leaflet carefully before you start taking 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 Griseofulvin is and what it is used for
2. Before you take Griseofulvin
3. How to take Griseofulvin
4. Possible side effects
5. How to store Griseofulvin
6. Further information

1. WHAT GRISEOFULVIN IS AND WHAT IT IS USED FOR

Griseofulvin 500mg Tablets, contain an anti-fungal agent called Griseofulvin. Griseofulvin kills the fungi that cause infections of the hair, skin, scalp, groin (“jock itch”), feet (“athlete’s foot”), and nails-ringworm. It does this by being incorporated in the skin, hair and nails, which takes the same time as they take to grow. This is why treatment lasts for a long time.

2. BEFORE YOU TAKE GRISEOFULVIN

Do not take Griseofulvin

- if you are allergic (hypersensitive) to griseofulvin or any of the other ingredients of the tablets-(see section 2)
- if you suffer from a rare disease called porphyria
- if you suffer from a rare painful skin and tissue disease called Systemic Lupus Erythematosus, or SLE
- if you have severe liver disease
- if you are pregnant, or you think you might be pregnant, or you are planning to get pregnant
- if you are breastfeeding

If any of the above apply to you, **do not** take the tablets and go back to your doctor.

Take special care with Griseofulvin

If any of the following points apply to you, you should discuss them with your doctor **before** starting to take Griseofulvin.

- If you have liver disease, your doctor may want to check on you while taking this medicine

- If you have had an allergic (hypersensitivity) reaction previously to penicillin or to cephalosporins, both types of antibiotic. There is a possibility you may be sensitive to griseofulvin
- If you are relying on oral contraception, the “pill”, griseofulvin may prevent it working. All sexually active patients should use additional barrier contraception, such as condoms, throughout griseofulvin therapy, and for four weeks (female) and 6 months (male) after stopping the therapy
- If you are a man planning to father a child, griseofulvin may damage your sperm. You should not father a child while taking griseofulvin and for **six** months after you have stopped taking it. You and your partner should use additional contraceptive measures to prevent pregnancy during this period.
- If you suffer from a rare painful skin and tissue disease called Systemic Lupus Erythematosus, or SLE
- Alcoholic drinks, and anything containing alcohol, should be avoided while you are taking Griseofulvin. Griseofulvin may make the alcohol affect you more. Alcohol and griseofulvin may cause a disulfiram reaction-you will feel sick, may be sick, blush, have an irregular heart beat, and chest and / or abdominal pain.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking Griseofulvin. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- Griseofulvin may result in the overgrowth of non-susceptible organisms, i.e bacteria or yeasts, or non-dermatophyte fungi, that are often cofactors in tinea infections, especially tinea pedis. Additional therapy is required to control or eradicate such organisms, as griseofulvin is ineffective.

Taking 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. It is especially important to tell your doctor if you are taking any of the following:

- ciclosporin, a medicine used after organ transplantation, it may not work as well
- any medicines to thin your blood, such as warfarin, your dose may need to be increased, and the doctor will want to check on you during treatment, and for 8 days after finishing treatment with griseofulvin
- methadone, used to treat addiction, or as a pain killer, the dose may need to be increased to maintain the same effect
- oral contraceptives-it may not work as well, and as you should not become pregnant during treatment with griseofulvin, you should use additional contraceptive measures, such as a condom
- barbiturates, such as phenobarbital, used to treat convulsions or as a sedative, it may prevent griseofulvin from being effective
- phenyl butazone, used to relieve pain or inflammation, it may prevent griseofulvin from being effective
- primidone, used to treat convulsions
- doxycalciferol, a vitamin D supplement
- medicines for sedation, or relief of anxiety, as they may prevent griseofulvin from being effective

Taking Griseofulvin with food and drink

For the best effects, Griseofulvin should be taken after a high fat meal. This helps to increase the absorption of griseofulvin into your body, so it can be effective against the infection and also reduce stomach discomfort.

Alcoholic drinks, and anything containing alcohol, should be avoided while you are taking Griseofulvin. Griseofulvin may make the alcohol affect you more. Alcohol and griseofulvin may cause a disulfiram reaction-you will feel sick, may be sick, blush, have an irregular heart beat, and chest and / or abdominal pain.

Pregnancy and breast-feeding

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

If you are pregnant, or think you might be pregnant-**do not take Griseofulvin** - see your doctor. It may harm your baby.

If you are taking griseofulvin and you **get** pregnant-see your doctor immediately.

Griseofulvin stops oral contraceptives working as effectively, so you should use additional contraception, such as a condom, while taking griseofulvin and for 4 weeks afterwards.

If you are breastfeeding-**do not take Griseofulvin** - see your doctor.

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 TAKE GRISEOFULVIN

Always take Griseofulvin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual adult dose is 500 mg to 1000 mg a day, given as either a single dose, or as two equal doses.

For children, the dose depends on the age and the weight of the child, and is usually 10 mg / kilogram of body weight per day. The dose is usually given as two equal doses. Make sure you follow the instructions of the doctor.

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 take more Griseofulvin than you should

You should contact your doctor, or the nearest hospital at once, and follow their advice. Remember to tell them how many extra tablets have been taken, and if you are taking any other medicines.

If you forget to take Griseofulvin

If you forget to take a tablet, take it when you remember, and if it is not after a meal, drink a glass of milk.

If it is nearly time for your next tablet, do not take a double dose to make up for a forgotten tablet just carry on with your next dose as normal.

If you stop taking Griseofulvin

Do not stop taking Griseofulvin unless your doctor tells you to. You must keep taking it, even if you feel better, and the skin or nails or hair seem to be cured. You should keep taking it for at least 2 weeks after all signs of infection have gone. If you stop early, the infection may come back.

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

4. POSSIBLE SIDE EFFECTS

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

The most common effects are headache and stomach discomfort at the start of treatment, but these usually disappear on continuing treatment.

If you get any of the following rare, or very rare side effects, see your doctor immediately

Rare, affecting more than 1 in 10,000 patients, but less than 1 in 1,000 patients

- Low numbers of certain types of blood cells, characterised by increased minor infections, sore throat, feeling tired and weak

- 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

Very rare, affecting fewer than 1 in 10,000 patients

- Changes to your liver, with signs such as lower back pain, very pale urine, yellowing of the skin and / or the whites of the eyes

Common, affecting more than 1 in 100 patients, but less than 1 in 10 patients

- Headache
- Diarrhoea, being sick, feeling sick, stomach discomfort

Uncommon, affecting more than 1 in 1000 patients, but less than 1 in 100 patients

- Lack of co-ordination, confusion, dizziness, drowsiness, sleeplessness, irritability, tingling and numbness in fingers and toes
- Anorexia, changes in taste sensation
- Blistering and peeling of the skin, lumpy skin, with or without a weeping liquid, reddening and burning of the skin-**you should contact your doctor immediately**

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 GRISEOFULVIN

Keep out of the reach and sight of children.

Do not use Griseofulvin after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

To be used within 6 months after first opening the container.

Do not store above 25°C.

After opening the container, screw the cap back tightly after every use.

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 Griseofulvin contains

- The active substance is Griseofulvin 500 mg in each tablet.
- The other ingredients are: maize starch, microcrystalline cellulose, sodium laurilsulphate, povidone, magnesium stearate, hypromellose, ethylcellulose, polysorbate 80, and propylene glycol.

What Griseofulvin looks like and contents of the pack

Griseofulvin 500mg Tablets are white to off white, round, biconvex film coated tablets.

They are packed in a plastic tablet container with a plastic screw cap. Containers of 90 tablets are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Brown & Burk IR Limited
22 Northumberland Road,
Ballsbridge, Dublin 4, Ireland

Manufacturer

Brown & Burk UK Ltd

5 Marryat Close

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UK.

Name of the product in different member states of the EEA:

United Kingdom Griseofulvin 500 mg Tablets

Ireland Griseofulvin 500 mg Film-coated Tablets

This leaflet was last updated in 12/2020.