

GRISOVIN

griseofulvin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GRISOVIN.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with GRISOVIN against the benefits it is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What is GRISOVIN

The name of your medicine is GRISOVIN.

GRISOVIN contains the antifungal griseofulvin.

This medicine is available in two strengths:

Grisovin 125 mg uncoated tablets and Grisovin 500 mg uncoated tablets.

What is it used for

GRISOVIN is used to treat tinea, a fungal infection.

It is only used when other antifungal treatments, such as tinea creams or powders, have not worked.

GRISOVIN will not work for bacterial or viral infections.

Tinea may occur in the skin of the body, scalp, hair or nails. GRISOVIN works by helping newly formed skin, hair and nails to resist attack by fungi. As the new tissue (keratin) grows, the old infected keratin is cast off. That is why it is important to continue treatment until all the old infected tissue is gone.

Ask your doctor or pharmacist if you have any questions about why GRISOVIN has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take it

Before taking GRISOVIN, you must tell your doctor if you:

- have ever had an allergic reaction to any of the ingredients listed at the end of this leaflet
- are or may become pregnant
- are breast-feeding
- planning to father a child
- are on a low fat diet
- have any other health problems, especially liver disease, lupus (systemic lupus erythematosus) or porphyria (a blood disease)

GRISOVIN may reduce the effectiveness of oral contraceptives. Extra contraceptive precautions (e.g. condom) should be used during your treatment and for a month after stopping GRISOVIN.

This medicine may cause birth defects. It must not be used during pregnancy. If you intend to become pregnant, you should delay pregnancy until one month after stopping treatment.

GRISOVIN may cause abnormalities in sperm cells. Men should not father children until at least six months after stopping treatment.

Do not use GRISOVIN if the packaging shows sign of tampering or the seal is broken.

Do not use it after the expiry date printed on the pack has passed.

It may have no effect at all, or worse, it may give an entirely unexpected effect if you use after the expiry date.

Taking other medicines

Tell your doctor if you are taking the following medicines:

- **Barbiturates**
- **Warfarin**
(an anticoagulant)
- **Oral contraceptives**

Tell your doctor or pharmacist if you are taking any other medicines.

This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other's work. Your doctor or pharmacist can tell you what to do when taking GRISOVIN with other medicines.

How to take it

How much to take

The following information lists the usual dose of GRISOVIN.

Adults - The usual dose is 500 mg per day. For nail infections, your doctor may prescribe up to 1000 mg daily until a response is apparent, at which time the dose may be reduced to 500 mg per day.

Children - The usual dose is 10 mg/kg body weight daily, taken in divided doses.

The dose will depend on the type of treatment required for a patient.

Your doctor will decide the number of doses needed each day and how long you will need to take GRISOVIN. These doses may differ from the usual doses shown in this leaflet.

If your dose is different to that described in this leaflet do not change it unless your doctor tells you to.

How to take it

Follow the instructions given by your doctor and pharmacist and read the label carefully.

Ask your doctor or pharmacist if you do not understand the instructions on the box or bottle.

When to take it

GRISOVIN tablets should always be taken after meals. They will work better if some fat is included in the meal (for example milk or ice cream).

You should tell your doctor if you are on a fat reduced diet.

How long to take it

Your doctor will advise you how long you will need to take GRISOVIN.

Generally, hair or skin infections need at least 4 weeks treatment. Infection of the toenails or fingernails may need 6 to 12 months treatment. Treatment should be continued for at least 2 weeks after all signs of the infection have disappeared.

If you forget to take it

If you forget to take GRISOVIN, take it as soon as possible with food.

If it is almost time for your next dose, skip the missed dose, and take the next dose at the usual time.

Do not take a double dose to make up for the missed dose.

If you have trouble remembering to take or give GRISOVIN, ask your pharmacist for some hints.

You should follow all advice from your doctor when being treated with this medicine. This information is not intended to replace your doctor's advice.

If you take too much (overdose)

Telephone your doctor or the Poisons Information Centre (Telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much GRISOVIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers of these places handy.

There are unlikely to be any serious problems from an overdose of GRISOVIN.

But you must consult your doctor or Poisons Information Centre.

While you are using it

Things you must do

GRISOVIN can increase the sensitivity of the skin 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.

Oral contraceptives (birth control pills) containing oestrogen may not work properly if you take them while you are taking GRISOVIN. If you are taking oral contraceptives, you should use a different or additional means of birth control while you are taking this medicine and until one month after stopping treatment.

If you become pregnant while you are taking GRISOVIN tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking GRISOVIN.

Tell your doctor if, for any reason, you have not used this medicine exactly as prescribed. Otherwise, your doctor may think that the medicine was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking GRISOVIN until it is finished.

Your infection and symptoms may not clear completely.

Do not give your medicine to anyone else even if his or her symptoms seem similar to yours.

Things to be careful of

GRISOVIN may cause some people to feel drowsy or dizzy. Make sure you know how you react to this medicine before you drive a car, use machinery, or do anything else that could be dangerous if you are dizzy or are not alert.

GRISOVIN may increase the effects of alcohol. If taken with alcohol it may also cause fast heartbeat, flushing, increased sweating, or redness of the face. If you have this reaction, do not drink alcoholic beverages without first checking with your doctor.

To avoid reinfection, any clothes, towels, bed linen, shoes, headwear etc. that has come into contact with the affected area, should be cleaned thoroughly or disposed of. Where possible, clothing and linen should be washed with detergent and hot water and dried in the sun. You may use a tinea powder or cream to help reduce the spread of infected clothing and linen.

Side Effects

All medicines, including GRISOVIN, may cause unwanted side effects in some people.

If any of the following side effects are severe or are worrying you, tell your doctor:

- headache, which may be severe, but usually disappears as treatment is continued
- tiredness, drowsiness
- dizziness
- nausea, vomiting or thirst
- diarrhoea
- insomnia (trouble in sleeping)
- heartburn or flatulence ("wind")
- skin rash and skin eruptions

If you have any of the following side effects, tell your doctor as soon as possible, as you may need medical attention:

- mental confusion
- skin rash, hives or itching
- soreness or irritation of the mouth or tongue
- sore, creamy-yellow, raised patches in mouth
- numbness, tingling, pain or weakness in hands or feet
- sore throat and fever
- yellow eyes or skin
- swelling in the throat
- menstrual irregularities

GRISOVIN may cause other side effects not listed above. If you have any other side effects, tell your doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using it

Storage

Keep GRISOVIN where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Store GRISOVIN tablets in a dry place below 30°C.

Do not leave it in the car or on windowsills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using GRISOVIN or it has passed its expiry date, ask your pharmacist what to do with any left over.

Further Information

This is not all the information that is available on GRISOVIN. If you need more information, ask a doctor or pharmacist.

Product Description

What it looks like

- Grisovin 125 mg tablets are a white to off white, scored, uncoated tablet engraved with "G125" on one side, that contains 125 mg of griseofulvin. They are available in bottles of 100 tablets.
- Grisovin 500 tablets are a white to off white uncoated tablet engraved with "G500" on one side, that contains 500 mg of griseofulvin. They are available in blister packs of 28 tablets.

List of inactive ingredients

Grisovin 125 mg tablets contain the following inactive ingredients:

- maize starch
- povidone
- sodium lauryl sulfate
- potato starch
- magnesium stearate

Grisovin 500 tablets contain the following inactive ingredients:

- maize starch
- povidone
- sodium lauryl sulfate
- potato starch
- microcrystalline cellulose
- magnesium stearate

The Australian Product Registration numbers are:

- AUST R 12512 for GRISOVIN 125 mg tablets
- AUST R 157849 for GRISOVIN 500 mg tablets

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

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