

GRISOVIN Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using GRISOVIN?

GRISOVIN contains the active ingredient griseofulvin. 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.

For more information, see Section [1. Why am I using GRISOVIN?](#) in the full CMI.

2. What should I know before I use GRISOVIN?

Do not use if you have ever had an allergic reaction to griseofulvin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use GRISOVIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GRISOVIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use 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.

More instructions can be found in Section [4. How do I use GRISOVIN?](#) in the full CMI.

5. What should I know while using GRISOVIN?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using GRISOVIN.• 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. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking this medicine until it is finished.• Do not give your medicine to anyone else even if his or her symptoms seem similar to yours. |
| Driving or using machines | <ul style="list-style-type: none">• 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. |
| Drinking alcohol | <ul style="list-style-type: none">• GRISOVIN may increase the effects of alcohol.• Tell your doctor if you drink alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• Store below 30°C. |

For more information, see Section [5. What should I know while using GRISOVIN?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache, tiredness, drowsiness, dizziness, nausea, vomiting, thirst, diarrhoea, insomnia, heartburn, flatulence, skin rash or skin eruptions. Serious side effects include mental confusion, skin rash, hives, itching, soreness or irritation of the mouth or tongue, oral thrush, numbness of hands or feet, sore throat and fever, yellow eyes or skin, swelling in the throat or menstrual irregularities.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

GRISOVIN Tablets

Active ingredient: *griseofulvin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GRISOVIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GRISOVIN.**

Where to find information in this leaflet:

- [1. Why am I using GRISOVIN?](#)
- [2. What should I know before I use GRISOVIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use GRISOVIN?](#)
- [5. What should I know while using GRISOVIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using GRISOVIN?

GRISOVIN contains the active ingredient griseofulvin. GRISOVIN is antifungal medicine.

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.

2. What should I know before I use GRISOVIN?

Warnings

Do not use GRISOVIN if:

- you are allergic to griseofulvin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant or may become pregnant.
- you are breast-feeding.
- you are planning to father a child.
- you are on a low fat diet.
- you have any other health problems, especially liver disease, lupus (systemic lupus erythematosus) or porphyria (a blood disease).
- the expiry date (EXP.) printed on the pack has passed.
- the packaging shows sign of tampering or the seal is broken.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant, breastfeeding or intend to become pregnant or breastfeed.

This medicine may cause birth defects. 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.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with GRISOVIN and affect how it works. These include:

- barbituates
- warfarin (an anticoagulant)
- oral contraceptives.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GRISOVIN.

4. How do I use GRISOVIN?

- 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.

How much to take

- 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.

When to take GRISOVIN

- 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

- 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 use GRISOVIN

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 dose you missed and take your next dose when you are meant to.

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

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 use too much GRISOVIN

If you think that you have used too much GRISOVIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

There are unlikely to be any serious problems from an overdose of GRISOVIN. But you must consult your doctor or Poisons Information Centre.

5. What should I know while using GRISOVIN?

Things you should do

- 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.

Remind any doctor, dentist or pharmacist you visit that you are using GRISOVIN.

Things you should 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.

Be careful of

- 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 estrogen 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 this medicine and until one month after stopping treatment.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GRISOVIN affects you.

GRISOVIN may cause some people to feel drowsy or dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

Follow the instructions in the carton or bottle on how to take care of your medicine properly.

Store it in a cool dry place below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• 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 | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">• 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 | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What GRISOVIN contains

125 mg tablets

| | |
|---|--|
| Active ingredient (main ingredient) | griseofulvin, 125 mg |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• maize starch• povidone• sodium lauryl sulfate• potato starch• magnesium stearate |

500 mg tablets

| | |
|---|---|
| Active ingredient (main ingredient) | griseofulvin, 500 mg |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• maize starch• povidone• sodium lauryl sulfate• potato starch• microcrystalline cellulose• magnesium stearate |

Do not take this medicine if you are allergic to any of these ingredients.

What GRISOVIN looks like

GRISOVIN 125 mg tablets: a white to off white, scored, uncoated tablet engraved with “G125” on one side. They are available in bottles of 100 tablets (AUST R 12512).

GRISOVIN 500 mg tablets: a white to off white uncoated tablet engraved with “G500” on one side. They are available in blister packs of 28 tablets (AUST R 157849).

Who distributes GRISOVIN

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

www.aspenpharmcare.com.au

This leaflet was prepared in October 2023.