

KRISOVIN TABLET

Griseofulvin (500mg)

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What Krivosin is used for

Krivosin contains the antifungal griseofulvin. Krivosin 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. Krivosin will not work for bacterial or viral infections.

How Krivosin works

Tinea may occur in the skin of the body, scalp, hair or nails. Krivosin 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 Krivosin has been prescribed for you.

Before you use Krivosin

- When you must not use it

Before taking Krivosin, 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
- have any other health problems, especially liver disease and lupus (systemic lupus erythematosus).

Krivosin may reduce the effectiveness of oral contraceptives.

You are advised to use an alternate or additional method of contraception while taking griseofulvin concurrently with estrogen-containing oral contraceptives and for 1 month after stopping griseofulvin.

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.

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

Do not use Krivosin 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.

- Before you start use it

Tell your doctor if you are taking the following medicines:

- Barbiturates
- Warfarin (an anticoagulant)
- Oral contraceptives

Complete blood count, serum creatinine concentration, urinalysis and hepatic function determinations are recommended at periodic intervals during therapy for certain individuals.

Tell your doctor immediately if you are pregnant or plan to become pregnant, or are breast-feeding or plan to breastfeed.

Your doctor can discuss with you the risks and benefits involved. If you have not told your doctor about any of the above, tell him/her before you start taking Krivosin.

- Taking other medicines

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

These medicines may be affected by Krivosin or may affect how well Krivosin works. You may need different amounts of your medicines, or you may need to take different medicines.

Anticoagulant effects may be decreased when used concurrently with griseofulvin due to accelerated metabolism of anticoagulants.

Antifungal effects of Krivosin may be decreased when it is used concurrently with primidone or barbiturates (for seizures), especially phenobarbital, because of impaired absorption, resulting in decreased concentrations in blood. Although the effect of decreased concentrations on therapeutic response has not been established, concurrent use is preferably avoided.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Krivosin.

How to use Krivosin

- How much to use

Adults - The usual dose is 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 an individual. Your doctor will decide the number of doses needed each day. These doses may differ from the usual doses shown in this leaflet.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the

instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Krivosin 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 use it

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

- If you forget to use it

Take the missed dose as soon as you remember, with food. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

Consult your doctor or pharmacist on what you should do if you forget to use it. If you have trouble remembering to take or give Krivosin, ask your pharmacist for some hints.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department at the nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Krivosin 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.

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

If you experienced a severe skin reaction, including bumps under the skin, blisters, redness and peeling with or without fever, swollen glands and abnormal blood test

results, see your doctor straight away.

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 the medicine unless advised by your doctor. Your infection and symptoms may not clear completely.

Do not take any new medicines without consulting your doctor.

Do not give Krivosin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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

To avoid re-infection, 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 and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

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
- dizziness
- nausea, vomiting or thirst
- dry mouth
- altered taste sensation
- diarrhoea
- trouble in sleeping
- 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
- numbness, tingling, pain or weakness in hands or feet
- sore throat and fever
- yellow eyes or skin
- swelling in the throat

Rare skin reactions which may be serious: widespread rash with blisters and peeling of the skin, especially around the mouth, nose and in the genital area causing severe skin peeling, fever, enlargement of the lymph nodes, or abnormal blood test (elevated eosinophil level or liver enzyme level). If you have such signs, consult your doctor immediately.

Krivosin may cause other side effects not listed above. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumer→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Krivosin

- Storage

Keep Krivosin in a cool dry place where the temperature stays below 30°C. Protect from light.

Keep your Krivosin in the pack until it is time to take them. If you take the tablets out of the pack, they may not be kept well.

Do not store Krivosin or any other medicine in the bathroom or near a sink.

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

Keep it where children cannot reach it. A locked cupboard at least one-and a half metres above the ground is a good place to store medicines.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Krivosin Tablet: A 12mm diameter, round, convex, scored, marked 'UP 500' white tablet.

- Ingredients

- Active ingredient:
Each tablet of Krivosin contains 500mg of griseofulvin BP.
- Inactive ingredients:
 - Sodium Starch Glycolate
 - Tween 80
 - Corn Starch
 - Lactose Monohydrate
 - Magnesium Stearate

- MAL number:

MAL19860847AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd.
Lot No. 2 & 4, Jalan P/7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor, Malaysia.

Product Registration Holder

Duopharma Manufacturing (Bangi) Sdn Bhd.
Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor, Malaysia.

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