

Rimstar 150 mg/75 mg/400 mg/275 mg Film-coated Tablets

rifampicin / isoniazid / pyrazinamide / ethambutol hydrochloride



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

1. What Rimstar is and what it is used for
2. What you need to know before you take Rimstar
3. How to take Rimstar
4. Possible side effects
5. How to store Rimstar
6. Contents of the pack and other information

1. What Rimstar is and what it is used for

Rimstar belongs to a group of medicines called antituberculosis agents. It is a fixed combination of four very effective antituberculosis agents. It is used to treat infections caused by mycobacteria. These mycobacteria cause tuberculosis. Rimstar is used for the initial treatment of tuberculosis.

2. What you need to know before you take Rimstar**Do not take Rimstar:**

- if you are allergic (hypersensitive) to rifamycins, isoniazid, pyrazinamide, ethambutol hydrochloride or to any of the ingredients of this medicine (listed in section 6).
- if you have acute liver problems or previously have had a liver problem which was caused by drugs
- if you are known to have a condition called porphyria
- if you have acute gouty arthritis
- if you have severe kidney problems
- if you are currently taking any of the following medications:
 - voriconazole
 - protease inhibitors except ritonavir when prescribed to you at full dose or 600 mg twice daily.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rimstar

Do not take Rimstar if any of the above apply to you.

If you are not sure about anything, ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rimstar. Tell your doctor if you have one of the following illnesses before taking this medicine:

- Liver problems and chronic liver disease
- Kidney problems
- Gout
- Diabetes mellitus
- Epilepsy
- Inflammation of peripheral nerves or the optic nerve
- Eye defects
- Chronic alcoholism
- Underfeeding

You should not take Rimstar if your body weight is below 30 kg.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Rimstar treatment. Stop taking Rimstar and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

You should not interrupt treatment with Rimstar without consulting your doctor.

You should employ additional means of contraception apart from taking the contraceptive pill as long as you take Rimstar.

Other medicines and Rimstar:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines obtained without a prescription.

Tell your doctor if you take one of the following medicines:

- You must not take Rimstar with any of the following medications:
- voriconazole
 - protease inhibitors except ritonavir
- if you are prescribed a full dose or 600 mg twice daily

- You should not take Rimstar with any of the following medications:
- nevirapine
 - simvastatin
 - ritonavir
 - oral contraceptives. You should use additional means of contraception as long as you take Rimstar.

Tell your doctor also if you take one of the following medicines:

- **Medicines for irregular heart beats** like class Ia antiarrhythmics (quinidine, disopyramide), propafenone, mexiletine, tocainide, lorcaïnide
- **Medicines for the heart or blood pressure:** calcium antagonists (such as diltiazem, nifedipine, verapamil, nimodipine, isradipine, nicardipine, nisoldipine, amlodipine), digitoxin, digoxin, carvedilol, digoxin, beta-blockers (such as bisoprolol, metoprolol, propranolol, carvedilol), losartan,

imidapril, enalapril

- **Diuretics** like eplerenone
- **Medicines to suppress the immune system** like ciclosporin, tacrolimus, sirolimus, leflunomide, azathioprine
- **Corticosteroids**
- **Medicines to treat fungal infections** (antifungals like fluconazole, itraconazole, ketoconazole, voriconazole, terbinafine)
- **Antibiotics** like clarithromycin, telithromycin, dapsone, doxycycline, fluoroquinolones, chloramphenicol, linezolid
- **Medicines to treat malaria:** atovaquone, quinine
- **Medicines for your mood** like haloperidol, clozapine, aripiprazole, tricyclic antidepressants (like amitriptyline, nortriptyline),
- **Medicines to prevent blood clots** like oral anticoagulants, warfarin,
- **Hormone treatments** like antioestrogens (such as gestrione, tamoxifene, toremifene) estrogens and progestagens given as hormonal replacement therapy or contraceptives, thyroid hormones (levothyroxine),
- **Medicines for pain** like morphine, etoricoxib, rofecoxib,
- **Medicines for AIDS** like saquinavir, indinavir, efavirenz, amprenavir, nelfinavir, azatanavir, lopinavir, zidovudine, nevirapine, stavudine,
- **Medicines for epilepsy** like tiagabine, carbamazepine, phenytoine, ethosuximide,
- **Medicines for sleeping disorders** like diazepam, benzodiazepines, buspirone, zopiclone, zolpidem, zaleplon, hexobarbital
- **Medicines for asthma** like theophylline,
- **Medicines for diabetes** like repaglinide and nateglinide or oral antidiabetics of sulfonylurea type,
- **p-aminosalicylic acid** (a medicine for tuberculosis and inflammatory bowel diseases)
- **Methadone** (a medicine for heroin addicts)
- **Medicines for stomach problems** like cimetidine,
- **Medicines for the treatment of high blood lipids** like clofibrate, fluvastatin, simvastatin
- **Medicines for sickness** like tropisetron, ondansetron
- **Medicines for narcosis** like halogenated volatile anesthetics
- **Medicines to treat cancer** like imatinib, gefitinib, irinotecan
- **Fexofenadine** (a medicine to treat hayfever)
- **Praziquantel** (a medicine against tapeworms)
- **Oral typhoid vaccine**

If you are currently taking any of these medicines, ask your doctor about switching to a different medicine while you are taking Rimstar. Often, there are other medicines you can take instead.

If you need to take a medicine for indigestion, such as an antacid, take your tablets at least one hour before the antacid.

The following examination methods cannot be performed or results have to be interpreted with care as long as you take Rimstar:

- radiographic examination of the gallbladder with contrast media
- microbiological determination of folic acid plasma concentrations
- microbiological determination of cyanocobalamin (vitamin B12) plasma concentrations

Rimstar with food and drink:

Do not drink any alcohol as long as you receive Rimstar. You should avoid food with a high content of histamine or tyramine (like matured cheeses, cured meat, some fish like tuna, salmon and mackerel, wine and beer. This food taken together with Rimstar may cause symptoms including headache, sweating, flushing, fast, uneven or forceful heartbeat (palpitations), dizziness, feel lightheaded or faint (due to low blood pressure). These foods should be avoided if you are receiving Rimstar. Your doctor will be able to advise further.

Take this medicine at least one hour before a meal.

Pregnancy and breast-feeding:

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. Your doctor will assess whether it is possible for you to continue with the treatment of Rimstar. If you take Rimstar during pregnancy, your doctor should give you vitamin B6 supplements during pregnancy and vitamin K supplements during the last month of pregnancy.

This medicine goes into human milk, therefore you should not take Rimstar when you are breast-feeding. It is important that you tell your doctor if you are breast-feeding or if you intend to breast-feed before receiving Rimstar.

Driving and using machines:

This medicine can cause side effects such as dizziness, confusion and blurred vision. This may make you less able to do certain things, such as driving or using machines.

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

3. How to take Rimstar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. These doses are for adults and children weighing more than 30 kg. Children weighing less than this should not take these tablets.

The recommended dose is:

Adults:

The amount of Rimstar people take can be different, and this depends on your body weight. Usually, you will be given the following number of tablets:

- If you weigh **30 kilograms (kg) to 39 kg** – take 2 tablets each day
- If you weigh **40 kg to 54 kg** – take 3 tablets each day
- If you weigh **55 kg to 70 kg** – take 4 tablets each day

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- If you weigh **more than 70 kg** – take 5 tablets each day.

Your doctor will prescribe the best dose for you.

Use in children

Rimstar is not recommended for children under 8 years of age or with a body weight of less than 30 kg.

Older people

Rimstar is well tolerated by most older patients, but you should inform your doctor if you are suffering from liver or kidney disease. In some cases your doctor may recommend that you take additional vitamin B6 as long as you take Rimstar.

Method of administration

You should take Rimstar once a day during the first two months of treatment.

Swallow these tablets whole with a drink of water.

Rimstar should be taken at least 1 hour before a meal.

Duration of treatment:

Rimstar is usually given for 2 months at the beginning of tuberculosis treatment. Your doctor will decide on the duration of treatment for you.

If you take more Rimstar than you should:

If you accidentally take one tablet too many, nothing is likely to happen. If you accidentally take several tablets too many, contact your doctor or talk to your nearest hospital casualty department immediately. If possible, take your tablets or the box with you to show the doctor what you have taken.

If you forget to take Rimstar:

If you forget to take a dose, take it as soon as possible. However, if it is nearly time for your next dose skip the missed dose and take the next tablet at the usual time.

If you stop taking Rimstar:

Always keep taking the tablets until the course is finished, even if you feel better. If you stop taking the tablets too soon, the infection may come back. Also, the bacteria may become resistant to the medicine.

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.

Serious side effects:

If you have any of the following symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden difficulty in breathing, speaking and swallowing; swelling of lips, tongue, face or neck (may affect up to 1 in 1,000 people)
- Extreme dizziness or collapse (may affect up to 1 in 1,000 people)
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis) (may affect up to 1 in 1,000 people)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome) (may affect up to 1 in 1,000 people)

If you experience any of the following side effects contact your doctor as soon as possible:

- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis, frequency not known).
- Yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (hepatitis, may affect up to 1 in 100 people).
- Diarrhoea that is serious, lasts a long time or has blood in it with stomach pain or fever: This can be a sign of serious bowel inflammation (may affect up to 1 in 1,000 people).
- Bleeding into the skin; if you continue taking Rimstar, you are at risk of brain haemorrhage (bleeding, may affect up to 1 in 1,000 people).
- Vision disturbances like blurred vision, eye pain, red-green colour blindness or even loss of vision (may affect up to 1 in 1,000 people).
- Shortage of white blood cells, accompanied by sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis, may affect up to 1 in 1,000 people).

These are all serious side effects. You may need urgent medical attention.

Other side effects:

Common side effects (may affect up to 1 in 10 people):

- Tiredness, drowsiness, headache, light-headedness, dizziness
- Damage of peripheral nerves
- Reddening of the eyes, permanent discoloration of soft contact lenses
- Nausea, vomiting, loss of appetite, abdominal pain, bloatedness, epigastric distress
- Flushing, itching with or without skin rash, nettle rash
- Allergic or other reactions like skin rash, fever, muscle or joint pain
- Increase of liver enzymes
- Disturbances of liver function which might show as loss of appetite, nausea, vomiting, fatigue, malaise and weakness
- Reddish discoloration of body fluids and secretions like urine, tear fluid, sweat, sputum, stools and saliva
- Increase in blood uric acid, acute gouty arthritis (chills, pain and swelling of joints, especially big toe, ankle or knee)

Uncommon side effects (may affect up to 1 in 100 people):

- Hallucinations, disorientation, confusion, malaise

Rare side effects (may affect up to 1 in 1,000 patients):

- Changes of white and red blood cell count, changes of platelet count, anaemia, disorders of blood clotting, swelling of spleen
- Oedema/swelling because of water retention
- Diarrhoea
- Menstrual disturbances, swelling of breast tissue in men, early puberty, difficulties in diabetes control, high blood sugar, Cushing's syndrome (disease caused by increase of corticosteroid hormones), induction of crisis in Addison's patients (patients with a special form of hormonal disorder)
- Psychosis, hyperactivity, euphoria, sleeplessness, convulsions
- Muscular weakness, myopathy, problems with the co-ordination of voluntary muscles (ataxia), increase in seizure frequency in epileptics
- Disturbances of vision, damage to the optic nerve
- Numbness, tingling, burning pain or weakness in hands or feet
- Gastritis, jaundice, enlargement of the liver, inflammation of the liver (in rare cases severe),
- Allergic and other reactions like dry mouth, heartburn, urination disorders, rheumatic syndromes and symptoms, pellagra (affection characterized by gastrointestinal disturbances, reddening of skin, nervous and mental disorders), swelling of lymph nodes, acne, skin rash, light sensitivity
- Elevation of kidney enzymes, acute kidney failure, inflammation of the kidney, problems with urination
- Induction of a condition called porphyria (a group of disorders characterized by light-sensitivity, skin lesions, anaemia, psychosis and acute abdominal pain)

Frequency not known:

- Inflammation of the blood vessels

If you resume therapy after an interruption of treatment with Rimstar, a so-called influenza-like syndrome may occur. It is characterized by fever, shivering and possibly headache, dizziness, bone and muscle pain. In rare cases bleeding into the skin, breathing difficulties, asthma-like attacks, anaemia, shock and kidney failure might develop.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Rimstar

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, label, or blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Blisters: Store in the original package in order to protect from moisture.

Containers: Keep the container tightly closed in order to protect from moisture.

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 protect the environment

6. Contents of the pack and other information

What Rimstar contains

The active substances are rifampicin, isoniazid, pyrazinamide and ethambutol hydrochloride. Each tablet contains 150 mg rifampicin, 75 mg isoniazid, 400 mg pyrazinamide and 275 mg ethambutol hydrochloride.

- *The other excipients are:*

Pre-gelatinised maize starch, maize starch, sodium laurilsulfate, microcrystalline cellulose, povidone K 30, crospovidone, magnesium stearate, talc, copovidone, hypromellose, talc, titanium dioxide (E 171), macrogol 400, macrogol 6000, iron oxide red (E 172).

What Rimstar looks like and contents of the pack

Rimstar, film-coated tablets are brown, ovaloid, biconvex film-coated tablets, plain on both sides.

The tablets are packed in aluminium/aluminium blisters or PVC/PE/PVDC-aluminium blisters which are inserted in a carton folder or white, opaque polypropylene container with polyethylene cap or a white, opaque polyethylene container with polypropylene cap.

Pack sizes:

Blisters:

30, 60, 120, 240, 672 or 1000 film-coated tablets.

Container:

500 film-coated tablets.

Pack sizes of 500 and 1000 film-coated tablets are intended for clinical use.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Sandoz Limited, Park View, Riverside Way
Watchmoor Park, Camberley, Surrey
GU15 3YL, United Kingdom

Manufacturer:

Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria.

or

Sandoz S.R.L., Str.Livezeni nr. 7a,
RO-540472 Targu-Mures, Romania.

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