

Package leaflet: Information for the patient

Rimactazid 150 mg / 75 mg, film-coated tablet rifampicin / isoniazid

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

1. What Rimactazid is and what it is used for

Rimactazid belongs to a group of medicines called antituberculosis agents. It is a fixed combination of two very effective antituberculosis agents which stop the growth of mycobacteria. These mycobacteria cause tuberculosis.

Rimactazid is used for the continuation phase treatment of tuberculosis.

2. What you need to know before you take Rimactazid

Do not take Rimactazid:

- if you are allergic (hypersensitive) to rifamycins, isoniazid, 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 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 Rimactazid
- if you are currently taking any of the following medicines:
 - o sofosbuvir - antiviral medicine for treatment of hepatitis C virus infections
 - o cabotegravir, fostemsavir, lenacapavir – HIV medicines
 - o lurasidoneas rifampicin may reduce the blood levels of several medicines including the above listed.

Do not take Rimactazid 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 Rimactazid.

Tell your doctor if you have one of the following illnesses before taking this medicine:

- Liver problems and chronic liver disease
- Kidney problems
- Diabetes mellitus
- Epilepsy
- Inflammation of peripheral nerves
- Chronic alcoholism
- Underfeeding

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

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

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

Serious skin reactions such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with Rimactazid treatment. Stop using Rimactazid and seek medical attention immediately if you notice any of the symptoms described in section 4.

Inform your doctor immediately while taking this medicine

- if your symptoms of tuberculosis return or get worse (see 4. Possible side effects)

Other medicines and Rimactazid:

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 Rimactazid 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 Rimactazid with any of the following medications:

- nevirapine
- simvastatin
- ritonavir
- oral contraceptives. You should use additional means of contraception as long as you take Rimactazid.

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, lorcinide

- **Medicines for the heart or blood pressure:** calcium antagonists (such as diltiazem, nifedipine, verapamil, nimodipine, isradipine, nicardipine, nisoldipine, amlodipine), digitoxin, digoxin, beta-blockers (such as bisoprolol, metoprolol, propranolol, carvedilol), losartan, imidapril, enalapril
- **Diuretics** like eplerenone
- **Medicines to suppress the immune system** like ciclosporine, tacrolimus, sirolimus, leflunomide, azathioprine
- **Corticosteroids**
- **Medicines to treat fungal infections** (antifungals like fluconazole, itraconazole, ketoconazole, voriconazole, terbinafine)
- **Antibiotics** like clarithromycin, telithromycin, dapson, 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 gestrinone, 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, 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 heroine addicts)
- **Medicines for stomach problems** like cimetidine,
- **Medicines for the treatment of high blood lipids** like cloifibrate, 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 Rimactazid. 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 Rimactazid:

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

Rimactazid with food and drink:

Do not drink any alcohol as long as you receive Rimactazid.

You should avoid food with a high content of tyramine (like cheese, red wine) or histamine (like tuna fish). This food taken together with Rimactazid may lead to headache, palpitations or flushing.

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 Rimactazid.

This medicine goes into human milk, therefore you should not take Rimactazid 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 Rimactazid.

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.

Rimactazid contains sodium:

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 Rimactazid

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

Your doctor will prescribe the best dose for you.

Use in children

Rimactazid is not recommended for children under 6 years of age or with a body weight of less than 30 kg.

Older people

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

Method of administration

You should take Rimactazid once a day during the continuation phase of treatment.

Swallow these tablets whole with a drink of water.
Rimactazid should be taken at least 1 hour before a meal.

Duration of treatment:

Rimactazid is usually given in the continuation phase of treatment for 4 months. Your doctor will decide on the duration of treatment for you.

If you take more Rimactazid 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 Rimactazid:

If you forgot 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.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Rimactazid:

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)

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).
- Severe extensive skin damage (separation of the epidermis and superficial mucous membranes) (toxic epidermal necrolysis, TEN, may affect up to 1 in 1,000 people)
- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome, may affect up to 1 in 1,000 people)
- 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 Rimactazid, you are at risk of brain hemorrhage (bleeding, 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 10,000 people).

- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis, frequency not known).
- Lupus-like syndrome, causing symptoms such as swollen joints, tiredness and rashes (frequency not known).

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
- 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
- Paradoxical drug reaction: symptoms of tuberculosis can return, or new symptoms can occur after initial improvement during treatment. Paradoxical reactions have been reported as early as 2 weeks and as late as 18 months after beginning anti-tuberculosis treatment. Paradoxical reactions are typically associated with fever, swollen lymph nodes (lymphadenitis), breathlessness, and cough. Patients with paradoxical drug reaction can also experience headaches, loss of appetite, and weight loss.

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

- Changes of white and red blood cell count, changes of platelet count, anemia
- 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 syndrome (disease caused by increase of corticosteroid hormones), induction of crisis in Addison patients (patients with a special form of hormonal disorder)
- Convulsions, confusion, psychoses, hyperactivity, euphoria, sleeplessness
- Muscular weakness, myopathy, problems with the coordination of voluntary muscles (ataxia), increase in seizure frequency in epileptics
- Disturbances of vision, damage to the optic nerve
- Gastritis, jaundice, 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, neural and mental disorders), swelling of lymph nodes, acne, skin rash
- Elevation of kidney enzymes, acute kidney failure, inflammation of the kidney
- Induction of a condition called porphyria (a group of disorders characterized by light-sensitivity, skin lesions, anemia, psychosis and acute abdominal pain)

Frequency not known:

- Inflammation of the blood vessels

If you resume therapy after an interruption of treatment with Rimactazid, 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, anemia, shock and kidney failure might develop.

Reporting of side effects

If you get any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rimactazid

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.

Blisters: Do not store above 25°C.

Containers: Do not store above 30 °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 Rimactazid contains**

- The active substances are rifampicin and isoniazid. Each film-coated tablet contains 150 mg of rifampicin and 75 mg of isoniazid.

- The other ingredients are: pregelatinised maize starch, maize starch, sodium laurilsulfate, crospovidone, magnesium stearate, talc, copovidone, hypromellose 3 cPs, hypromellose 6 cPs, hypromellose 50 cPs, titanium dioxide (E 171), macrogol 400, macrogol 6000, red iron oxide (E 172).

What Rimactazid looks like and contents of the pack

Round, biconvex, dark-pink film-coated tablets, 9.5 ± 0.4 mm in diameter, plain on both sides.

Rimactazid 150 mg/75 mg, film-coated tablets may be packed in the following pack sizes:

Carton box with blisters containing:

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

White, opaque polypropylene container with polyethylene cap containing:

500 film-coated tablets.

White, opaque polyethylene container with polypropylene cap containing:
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

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Rimactazid
France:	Rimactazid 150 mg/75 mg, comprimé pelliculé
Norway:	Rimactazid 150 mg/75 mg, tablett, filmdrasjert
Sweden:	Rimactazid 150 mg/75 mg, filmdragerad tablett
United Kingdom:	Rimactazid 150 mg/75 mg, film-coated tablet

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