

RIFAPEX 150MG DISPERSIBLE TABLETS

Rifapentine Dispersible Tablets 150 mg

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What Rifapex is used for

Rifapex is indicated in combination with other tuberculosis medicines for the initial treatment of tuberculosis due to *Mycobacterium tuberculosis*.

It is also indicated together with other medicines for the prevention of tuberculosis in persons at risk.

How Rifapex works

Rifapex is always given together with other medicines to treat or prevent tuberculosis. Your healthcare provider has chosen the combination that is right for your condition. Rifapex contains the active substance rifapentine and works by stopping the bacteria responsible for the disease from multiplying in the body.

Before you use Rifapex

- When you must not use it

Do not take this medicine if you:

- are allergic (hypersensitive) to rifapentine or another rifamycin antibiotic or any of the other ingredients of this medicine (listed in Product Description)
- have or had serious liver problems
- have ever had liver problems or drug fever or chills after taking rifapentine

- Before you start to use it

Check with your doctor or pharmacist before taking Rifapex if you are taking certain medicines:

- HIV infection medicines: atazanavir, bicitgravir/emtricitabine/tenofovir alafenamide, darunavir-, doravirine,

elvitegravir/cobicistat, etravirine, fosamprenavir, lopinavir, nevirapine, rilpivirine, ritonavir, tipranavir

- Chronic hepatitis C medicines: daclatasvir, elbasvir/grazoprevir, glecaprevir/pibrentasvir, ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir, sofosbuvir
- Malaria medicines: artemisinin and its derivatives (artemether, artemotil, artesunate, dihydroartemisinin

Unsuitable for phenylketonurics.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- 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.

Inform your doctor or pharmacist if you are taking:

- antacids
- amlodipine, atenolol, nifedipine, propranolol
- digoxin, diltiazem, disopyramide, mexiletine, propafenone, quinidine, tocainide, verapamil
- clopidogrel, warfarin
- atorvastatin, clofibrate, simvastatin
- eplerenone
- zopiclone, zolpidem
- carbamazepine, lamotrigine, phenobarbital, phenytoin, valproic acid
- amitriptyline, nortriptyline
- riluzole
- aripiprazole, chlorpromazine, clozapine, haloperidol
- diazepam, midazolam, nitrazepam

- fluconazole, itraconazole, ketoconazole, voriconazole
- chloramphenicol, ciprofloxacin, clarithromycin, cotrimoxazole, dapsone, doxycycline, levofloxacin
- bedaquiline, ethionamide, p-aminosalicylic acid
- cyclosporine, sirolimus, tacrolimus
- praziquantel
- atovaquone
- chloroquine, lumefantrine, mefloquine, quinine
- ethinyloestradiol, levonorgestrel, norethindrone
- gestrinone, tamoxifen, toremifene
- imatinib, irinotecan
- levothyroxine
- codeine, fentanyl, morphine, paracetamol, pethidine
- prednisolone
- methadone
- glibenclamide, gliclazide, glimepiride, glipizide, glyburide, repaglinide
- theophylline
- sildenafil

Other medicines used for TB such as p-aminosalicylic acid (PAS). PAS and Rifapex should be taken at least 8 hours apart.

How to use Rifapex

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.

- How much to use

For treatment of tuberculosis (TB):

The dose of Rifapex is 8 tablets once daily. When used for treatment in this way, Rifapex is only suitable for people aged 12 years or older. It is taken together with other tuberculosis medicines.

Prevention of tuberculosis

Once weekly dosing

For prevention of tuberculosis, Rifapex is usually given once a week for a period of

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3 months, i.e., 12 doses. It is given with another tuberculosis medicine called isoniazid.

The number of tablets to take each week depends on your age and weight.

For patients aged 2 to 14 years, the usual recommended dose is as follows:

- If your child weighs 10 to less than 16 kilograms, give 2 tablets (300 mg) once a week.
- If your child weighs 16 to less than 24 kilograms, give 3 tablets (450 mg) once a week.
- If your child weighs 24 to less than 31 kilograms, give 4 tablets (600 mg) once a week.
- If your child weighs 31 kilograms or more, give 5 tablets (750 mg) once a week.

For patients aged over 14 years and weighing at least 30 kg the usual recommended dose is 6 tablets of Rifapex weekly with isoniazid for 3 months.

Daily dosing

Your health care provider may recommend a shorter preventive treatment, where Rifapex is given in a recommended dose of 4 tablets (600 mg) daily, together with isoniazid, for one month. This shorter preventive treatment is for adults and children aged 13 years and older only.

Always take Rifapex as your health care provider advises and ask them if you are not sure how to take your tablets.

- When to use it

Always take with food.

Disperse tablets in at least 10 mL water (max 50 mL), stir, drink immediately, rinse cup and drink rinse water.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. 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.

- If you use too much (overdose)

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

Taking too much of this medicine may cause heartburn, headache and pruritus.

While you are using Rifapex

- Things you must do

Use your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If this medicine makes you feel dizzy. Do not drive or use machines and contact your doctor immediately.

Side effects

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

Very common or common side effects (may affect 1 in 10 to 1 in 100 people):

- Stomach or gut problems such as diarrhoea, indigestion, nausea, vomiting or stomach pain.
- Fever, chills, feeling tired or weak.
- Headache or dizziness.
- Joint or muscle pain.
- Rash, itching or hives (red itchy bumps).
- Red eyes (conjunctivitis).
- Changes in liver blood tests.

Serious but less common side effects that you should recognise and report immediately:

- Yellowing of the skin or eyes, dark urine, persistent nausea or abdominal pain (signs of liver problems).
- Severe rash with blisters or peeling skin, mouth sores, flu-like symptoms or swelling of the face or throat (possible severe skin reaction such as Stevens-Johnson syndrome or DRESS).
- Severe or persistent diarrhoea (possible Clostridioides difficile infection).
- Allergic reactions such as sudden drop in blood pressure, difficulty breathing, wheezing, or swelling of lips, tongue or throat.
- Numbness, tingling or weakness in hands or feet.
- Coughing up blood or trouble breathing.

The following serious and otherwise important adverse drug reactions are discussed. Their frequencies are unknown.

- Severe skin reactions such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS)
- Discoloration of body fluids
- Diarrhoea caused by the bacterium Clostridioides difficile
- Porphyria: a disease affecting the skin or nervous system caused by build-up in the body of substances called porphyrins

If you experience any of these serious symptoms, stop taking the medicine and contact your doctor immediately.

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

Storage and Disposal of Rifapex

- Storage

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

- colloidal silicon dioxide,
- calcium stearate.

Store below 30°C. Protect from excessive heat and moisture.

This medicine is essentially 'sodium-free'. It contains less than 1 mmol sodium (23 mg) per tablet.

- **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

- **MAL number:**

MAL*****

Product Description

- **What it looks like**

Rifapex is mottled red, round, uncoated tablets. They are flat on the top and bottom with a bevelled edge. The tablets have a break line on one side and are plain on the other side.

The break line can be used to divide Rifapex into equal halves.

Rifapex is provided in an aluminium foil strip packs, each containing 10 or 28 tablets. Available in packs of 10 x 10 or 1 x 28 tablets.

Rifapex is provided in an aluminium foil on aluminium foil blister cards, each containing 10 or 12 tablets. Available in packs of 10 x 10, 3 x 10 or 10 x 12 tablets.

- **Ingredients**

- Active ingredient

- Rifapentine

- Inactive ingredients

- microcrystalline cellulose,
- sodium starch glycolate,
- sodium lauryl sulfate,
- maize starch,
- disodium edetate.
- sodium ascorbate,
- hydroxypropylmethylcellulose,
- crospovidone,
- aspartame,
- trusil peppermint flavour,
- raspberry flavour,

Manufacturer

Lupin Limited
A-28/1, MIDC Area, Chikalthana,
Chhatrapati Sambhajnagar- 431210,
Maharashtra State,
India.

Product Registration Holder

Pahang Pharmacy Sdn.Bhd.
Lot 5979 Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor
Malaysia

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