

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB402 trade name][†]
Rifapentine

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB402 trade name] is and what it is used for
2. What you need to know before you take [TB402 trade name]
3. How to take [TB402 trade name]
4. Possible side effects
5. How to store [TB402 trade name]
6. Contents of the pack and other information

1. What [TB402 trade name] is and what it is used for

[TB402 trade name] is a medicine used to treat (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*.

[TB402 trade name] is also used to prevent TB if you are at high risk of infection.

[TB402 trade name] 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.

[TB402 trade name] contains the active substance rifapentine and works by stopping the bacteria responsible for the disease from multiplying in the body.

2. What you need to know before you take [TB402 trade name]

Do not take [TB402 trade name] if you:

- are allergic (hypersensitive) to rifapentine or another rifamycin antibiotic or any of the other ingredients of this medicine (listed in section 6)
- have liver problems
- have ever had liver problems or drug fever or chills after taking rifapentine
- are taking certain medicines:

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- **HIV infection medicines:** atazanavir, bictegravir/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)

Check with your health care provider if you are not sure.

Warnings and precautions

Liver disease

[TB402 trade name] may cause liver disease (hepatitis). When taking [TB402 trade name], your health care provider will monitor you regularly to check for any problems with your liver.

You should watch out for symptoms of liver damage, such as unexplained lack of appetite, nausea, vomiting, dark urine, yellow discolouration of the skin and the eyes (jaundice), rash, tingling in the hands and feet, persistent tiredness, weakness lasting longer than 3 days and abdominal (belly) pain and tenderness. If these occur, you should immediately tell your health care provider.

You may be at special risk for developing hepatitis if you:

- are older than 35 years
- drink alcoholic beverages daily (see '*[TB402 trade name] with food and drink*'))
- have a long-term liver disorder
- are a user of injection drugs (e.g., heroin)

If you are in one of these groups, your health care provider will check your liver function more often.

Furthermore, you will be carefully monitored if you:

- are on another long-term medication (see '*Other medicines and [TB402 trade name]*'))
- suffer from tingling in the hands and feet (peripheral neuropathy)
- are pregnant
- are HIV infected.

Severe skin reactions

Serious skin reactions such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome may happen in some people taking [TB402 trade name]. Stop taking [TB402 trade name] right away and tell your health care provider if you have any of the following symptoms: rash; red and painful skin; peeling or bleeding skin; sores or blisters on the inside of your mouth or lips; swollen face, lips, mouth tongue or throat; flu-like symptoms.

Allergic reactions and flu-like symptoms

If you get flu-like symptoms such as fever, headache and muscle aches, you should tell your health care provider, since [TB402 trade name] may be the cause. Signs and symptoms of an allergic reaction may include: low blood pressure (hypotension), hives, cough with wheezing, difficulty breathing, red eyes (conjunctivitis), lower blood platelet levels.

Diarrhoea

A type of diarrhoea called *Clostridioides difficile*-associated diarrhoea (CDAD) may occur during or after taking antibiotics, including [TB402 trade name]. The severity of CDAD can range from mild diarrhoea to severe diarrhoea that may cause death (fatal colitis). Tell your health care provider right away if you have diarrhoea while you take or after you stop taking [TB402 trade name].

Porphyria

Patients with a condition called porphyria may experience a worsening of symptoms.

Contraception

[TB402 trade name] may lower the effects of oral contraceptive pills. Therefore, a different or additional method of contraception (e.g. condoms, intra-uterine device, pessary) should be used during treatment with [TB402 trade name].

Addison's disease

[TB402 trade name] may lower the effects of corticosteroids used in Addison's disease, causing life-threatening effects (i.e., low pressure, low blood levels sugar, high blood levels of potassium).

Discolouration of body fluids

[TB402 trade name] may cause a reddish orange discolouration of body fluids such as urine, phlegm and tears. This is due to this medicine's active ingredient, rifapentine and does not require medical attention. Also, contact lenses or dentures may become permanently stained due to [TB402 trade name].

Interaction with laboratory tests

It is possible that [TB402 trade name] may interfere with some blood tests. If you need a blood test to check for folate or vitamin B12 levels tell your health care provider you are taking [TB402 trade name] as it may affect your results.

If you are not sure if any of the above applies to you, talk to your health care provider before taking [TB402 trade name].

Other medicines and [TB402 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

Medicines you must not take with [TB402 trade name]

- **You must not take [TB402 trade name] with** certain medicines for HIV infection, chronic hepatitis C infection and malaria. This is because [TB402 trade name] may significantly decrease the amount of these medicines in your blood, preventing them from working well enough. See the full list of these medicines above under '*Do not take [TB402 trade name] if you'*'.

Check with your health care provider if you are not sure.

Other medicines that can interfere with [TB402 trade name]

Where possible, you should not take [TB402 trade name] with other medicines that can cause damage to the liver, since their side effects may add up. Your health care provider will be able to advise you about any changes that may be needed to your treatment.

You should not take [TB402 trade name] with **antacids** used for indigestion.

Other medicines used for TB such as **p-aminosalicylic acid** (PAS). PAS and [TB402 trade name] should be taken at least 8 hours apart.

[TB402 trade name] may also interfere with a great number of other medicines, including, for instance:

- Medicines for **high blood pressure** such as amlodipine, atenolol, nifedipine, propranolol
- Medicines for **heart problems** or to control your heartbeat such as digoxin, antiarrhythmics (such as diltiazem, disopyramide, mexiletine, propafenone, quinidine, tocainide, verapamil)
- Medicines used to **thin the blood** such as clopidogrel, warfarin
- Medicines used to **lower cholesterol** such as atorvastatin, clofibrate, simvastatin
- **Water tablets** (diuretics) such as eplerenone

- Medicines for thought disorders known as ‘**antipsychotics**’ such as aripiprazole, chlorpromazine, clozapine, haloperidol
- Medicines to calm or **reduce anxiety** (hypnotics, anxiolytics) such as diazepam, midazolam, nitrazepam
- Medicines to help you **sleep** such as zopiclone, zolpidem
- Medicines used for **epilepsy** such as carbamazepine, lamotrigine, phenobarbital, phenytoin, valproic acid
- Some medicines used for **depression** such as amitriptyline, nortriptyline
- Riluzole - used for **motor neurone disease**
- Medicines used for **fungal infections** such as fluconazole, itraconazole, ketoconazole, voriconazole
- Medicines used for bacterial infections other than TB (**antibiotics**) such as chloramphenicol, ciprofloxacin, clarithromycin, cotrimoxazole, dapsone, doxycycline, levofloxacin
- Medicines used for **tuberculosis** such as bedaquiline, ethionamide, p-aminosalicylic acid
- Medicines used for **lowering your immune system** such as cyclosporine, sirolimus, tacrolimus
- Praziquantel - used for certain **worm infections**
- Atovaquone - used for **pneumonia**
- Medicines used in **malaria**: chloroquine, lumefantrine, mefloquine, quinine
- Some **hormone medicines** used for contraception such as ethinylestradiol, levonorgestrel, norethindrone
- Some hormone medicines (anti-estrogens) used for **breast cancer** or **endometriosis** such as gestrinone, tamoxifen, toremifene
- Some medicines used for **cancer** (cytotoxics) such as imatinib, irinotecan
- Levothyroxine (thyroid hormone) used for **thyroid problems**
- Medicines used for **pain** such as codeine, fentanyl, morphine, paracetamol, pethidine
- Corticosteroids used for **inflammation** such as prednisolone
- Methadone - used for **heroin withdrawal**
- Medicines used for **diabetes** such as glibenclamide, gliclazide, glimepiride, glipizide, glyburide, repaglinide
- Theophylline - used for wheezing or **difficulty in breathing**
- Sildenafil- used to treat **male sexual erection problems**

Pregnancy and breast-feeding

Ask your health care provider for advice before taking this medicine.

Tell your health care provider if you are pregnant or planning to become pregnant. [TB402 trade name] should not be taken during pregnancy as it can affect the growth of your unborn baby and may cause complications to the mother and baby after birth.

[TB402 trade name] may make the contraceptive “pill” work less well. This means you should change to a different type of contraception. You must use a reliable barrier method of contraception such as condoms or the “coil” while taking [TB402 trade name]. If you have any questions or are unsure about this talk to your health care provider.

You should not breast-feed if you are taking [TB402 trade name]. This is because small amounts may pass into the mothers' milk. If you are breast-feeding or planning to breast-feed, talk to your health care provider before taking any medicine.

Driving and using machines

You may feel dizzy while taking [TB402 trade name]. If this happens, do not drive or use any tools or machines.

Other ingredients of [TB402 trade name]

[TB402 trade name] also contains 9 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take [TB402 trade name]

Always take [TB402 trade name] exactly as your health care provider told you and finish the course. You should check with your health care provider if you are not sure.

Your health care provider will assign the dose of [TB402 trade name] appropriate for you. The following information includes only the average doses of this medicine. If your prescribed dose is different, do not change it unless your health care provider tells you to do so.

Treatment of tuberculosis

The dose of [TB402 trade name] is 8 tablets once **daily**. When used for treatment in this way, [TB402 trade name] 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, [TB402 trade name] is usually given **once a week** for a period of 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:

Body weight	Number of tablets
10 to less than 16 kg	2
16 to less than 24 kg	3
24 to less than 31 kg	4
31 kg and over	5

For *patients aged over 14 years* and weighing at least 30 kg the usual recommended dose is 6 tablets of [TB402 trade name] weekly with isoniazid for 3 months.

Daily dosing

Your health care provider may recommend a shorter preventive treatment, where [TB402 trade name] is given in a recommended dose of 4 tablets **daily**, together with isoniazid, for one month. This shorter preventive treatment is for adults and children aged 13 years and older only.

Always take [TB402 trade name] as your health care provider advises and ask them if you are not sure how to take your tablets.

How to take [TB402 trade name]

[TB402 trade name] should be taken with food.

Disperse the tablets in drinking water before taking the dose. Each tablet should be dispersed in a minimum of 10 mL water; the maximum volume of water recommended for dispersion of a dose is 50mL.

Instructions for taking [TB402 trade name] tablets

1. Look up the patient's weight.
2. Then look for the number of tablets that will be required for treatment or prevention of TB.
3. Place the required volume of water in a small, clean cup or bowl and add the required number of tablets.
4. Stir gently until the tablets disperse.
5. Drink the entire medicine mixture immediately.
6. Rinse the cup with a little additional water and drink this water.

If you take more [TB402 trade name] than you should

If you have taken too many tablets or if someone accidentally swallows some, you should contact your health care provider or the nearest hospital emergency department for further advice.

If you forget to take [TB402 trade name]

It is important that the patient takes the medicine regularly as prescribed.

If you forget to take a **daily** dose and there are more than 6 hours till your next dose, take the missed dose as soon as possible. Then continue your treatment as before. If there are less than 6 hours till your next dose, skip the missed dose. Don't take a double dose to make up for a missed dose.

If a **weekly** dose is missed but it is remembered within the next 2 days, take the dose immediately and continue the schedule as originally planned.

If the missed dose is remembered more than 2 days later, take the missed dose immediately and change the schedule for weekly intake to the day the missed dose was taken until treatment completion.

If 4 or more weekly doses are missed, see your health care provider who may restart the full preventive treatment.

If you vomit within 1 hour of taking [TB402 trade name], the dose should be repeated.

If you stop taking [TB402 trade name]

Keep taking the medicine for as long as your health care provider has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

You should not stop treatment unless your health care provider tells you to.

If you have any further questions on the use of this product, ask your health care provider.

4. Possible side effects

Like all medicines, [TB402 trade name] can cause side effects, although not everybody gets them.

The table below shows side effects that may be seen in patients taking [TB402 trade name]:

	May occur in at least 1 patient in 100	May occur in less than 1 patient in 100
Blood and lymphatic system disorders	Abnormal number of platelets High number of white blood cells Low red blood cells Swollen lymph nodes	Abnormal blood clotting Bleeding outside of blood vessels (haematoma purpura) Low white blood cells
Cardiovascular and vascular disorders		Fainting Inflammation of tissue surrounding the heart (pericarditis) Low blood pressure on standing Palpitations
Eye disorders	Infection of eye membrane (conjunctivitis)	
Gastrointestinal disorders	Diarrhoea Indigestion Nausea Stomach pain Vomiting	Constipation, Dry mouth Enlarged salivary glands Inflammation of digestive system Inflammation or irritation of the passage between mouth and stomach (oesophagitis) Pancreatitis
General disorders	Fever	Chest pain Chills Facial swelling caused by fluid retention Feeling jittery Feeling of tiredness Feeling of weakness
Hepatobiliary disorders	High liver function tests, e.g., elevated ALT, elevated AST	Enlarged liver Increased bilirubin Jaundice (yellowing of eyes, skin)
Immune system disorders	Allergic reaction	
Investigations	Blood urea increased	
Infections and infestations		Sore throat (pharyngitis) Vaginal yeast infections and other fungal infections Viral infection
Metabolism and nutrition disorders	Decreased appetite	Alkaline phosphatase increased Elevated blood glucose Elevated blood lipids Elevated potassium in the blood

		Gout
Musculoskeletal and connective tissue disorders	Joint pain Back pain	Damaged muscle tissue (rhabdomyolysis) Inflamed muscles Muscle pain
Nervous system disorders	Dizziness Headache	Fits (convulsion) Impaired voice Problems with nerves that cause numbness or muscle weakness Sleepiness Tingling sensation
Pregnancy and perinatal conditions		Miscarriage
Psychiatric disorders		Anxiety Confusion Depression Disorientation Suicidal thoughts
Renal and urinary disorders		Elevated urea, creatinine in the blood
Reproductive disorders		Inflamed vagina Itchy vagina Other vagina discharge Vaginal bleeding
Respiratory, thoracic and mediastinal disorders	Cough Coughing up blood	Accumulation of fluid in the larynx (voice box) Asthma Constriction of airways (bronchospasm) Increased sensitivity of airways Inflammation of lung tissue (pneumonitis) Laryngitis Nose bleeding Shortness of breath Sore throat
Skin disorders	Excessive sweating Itching Rash	Hives Skin discoloration

The following serious and otherwise important adverse drug reactions are discussed in section 2 ‘Warning and Precautions’. 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

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB402 trade name]

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

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

Do not use this medicine after the expiry date stated on the blister label and carton after {EXP}. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [TB402 trade name] contains

- The active ingredient is rifapentine.
- The other ingredients of [TB402 trade name] are microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulfate, maize starch, disodium edetate, sodium ascorbate, hydroxypropylmethylcellulose, crospovidone, aspartame, trusil peppermint flavour, raspberry flavour, colloidal silicon dioxide, calcium stearate

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB402 trade name] looks like and contents of the pack

[TB402 trade name] 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 [TB402 trade name] into equal halves.

[TB402 trade name] 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.

[TB402 trade name] is provided in an aluminium foil on aluminium foil blister cards, each containing 10 or 12 tablets. Available in packs of 10 x 10 or 10 x 12 tablets.

Supplier and Manufacturer

Supplier

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai
Maharashtra 400 055
India
Tel: 91-22-66402323
E-mail: globaltb@lupin.com

Manufacturer

Lupin Limited
A-28/1, MIDC Area, Chikalthana
Aurangabad 431 210
Maharashtra State
India
Tel: +91 240 6612444

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in December 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>