

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 tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*.

[TB402 trade name] is also used to prevent TB if there is a high chance you could catch it.

[TB402 trade name] is always given together with other medicines to treat or prevent tuberculosis. Your health care provider has chosen the combination that is right for your condition.

[TB402 trade name] contains the active substance rifapentine and works by stopping an enzyme that the bacteria need to reproduce and spread 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:
 - HIV infection medicines: atazanavir, bictegravir/emtricitabine/tenofovir alafenamide, darunavir, doravirine, elvitegravir/cobicistat, etravirine, fosamprenavir, lopinavir, nevirapine, rilpivirine, ritonavir, tipranavir

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

- Chronic hepatitis C medicines: daclatasvir, elbasvir/grazoprevir, glecaprevir/pibrentasvir, ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir, sofosbuvir

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

Warnings and precautions

Liver disease

Some TB medicines, including [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.

Speak with your health care provider straightaway if you:

- lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash

and you have any of the following:

- belly pain, usually on the right side and near the chest
- unexplained itching
- yellowing of the white parts of your eyes, your nails or your skin
- passing dark urine
- passing stools that are very pale.

These are signs of a problem with your liver, which can become serious.

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 or have previously had one
- are a user of recreational drugs by injection (e.g., heroin)

Furthermore, you will be carefully monitored if you:

- are pregnant or have recently had a baby
- 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. You should also tell them if you get an allergic reaction with symptoms like: low blood pressure (hypotension), hives, cough with wheezing, difficulty breathing and red eyes (conjunctivitis).

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 very severe diarrhoea that has been known to cause death (fatal colitis). Tell your health care provider right away if you have diarrhoea while you take or soon 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 substance, 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 and chronic hepatitis C infection. 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.

If you are also taking **p-aminosalicylic acid (PAS)** for TB, 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, clarithromycin, dapsone, doxycycline
- 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**: amodiaquine, chloroquine, lumefantrine, mefloquine, quinine, artemisinin. If you are being treated for malaria, your health care provider may reschedule your TB preventive treatment.
- Some **hormone medicines** used for contraception such as ethinylestradiol, levonorgestrel, norethindrone
- Some hormone medicines (anti-oestrogens) 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**
- Antacids – used for **heartburn or indigestion**

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. Information on the safe use of [TB402 trade name] during pregnancy is lacking. Your health care provider may therefore recommend another medicine if you are pregnant.

[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.

If you are taking [TB402 trade name] while breast-feeding, small amounts may pass into breast milk and may affect its colour. If you are breast-feeding or planning to breast-feed, talk to your health care provider before taking this medicine.

Driving and using machines

[TB402 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

Other excipients

This medicine 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]

Your health care provider will decide on the right doses and combination of medicines to treat or prevent your TB, based on your age, weight and condition.

Always take [TB402 trade name] exactly as your health care provider has told you and finish the course. You should check with your health care provider if you are not sure. Do not change it unless your health care provider tells you to do so.

Disperse the tablets in drinking water before taking the dose. See “**Instructions for taking [TB402 trade name] tablets**”, below.

For information on how to take the other medicines you need for your TB treatment, discuss with your health care provider and see the leaflets that come with those medicines as well.

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 and weighing more than 40 kg. 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, which means 12 doses in total. It is given with another tuberculosis medicine called isoniazid.

The number of tablets to take each week depends on your weight. The usual recommended dose is as follows:

Body weight	Usual recommended dose
3 to less than 6 kg	<i>If less than 3 months of age</i> 5 mL* once a week
	<i>3 months of age or more</i> 7 mL* once a week
6 to less than 10 kg	1½ tablets once a week
10 to less than 15 kg	2 tablets once a week
15 to less than 20 kg	3 tablets once a week
20 to less than 30 kg	4 tablets once a week
30 to less than 35 kg	5 tablets once a week
35 kg and over	6 tablets once a week

* Volume to be taken after dispersing one 150-mg rifapentine tablet in 10 mL of water. See below for more information on how to prepare this dose.

Once daily dosing

If you are 13 years old or more and weigh at least 25 kg, 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 1 month.

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. Take this leaflet and any remaining tablets with you so that you can easily describe what you have taken.

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.

Instructions for taking [TB402 trade name] tablets

[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 (which is about 2 teaspoonfuls); the maximum volume of water recommended for dispersion of a dose is 50mL (around 10 teaspoonfuls).

Instructions for taking [TB402 trade name] tablets in patients weighing 6 kg or more

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.

Instructions for giving [TB402 trade name] tablets in patients weighing 3 to 6 kg

You'll need:

- 1 tablet of [TB402 trade name]
- drinking water
- a 10-mL oral syringe
- a cup

1. Use the oral syringe to measure 10 mL of drinking water and put it into the cup.
2. Add 1 tablet and stir gently until the tablet is fully mixed.
3. Consider the child's age and then look for the volume that will be required in the above table.

4. Use the syringe to draw up the correct amount of liquid mixture and give it to the child straight away.
5. Throw away any liquid left in the cup.

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 following side effects have occurred in patients taking rifapentine with other TB medicines (including the medicine with isoniazid), and may be seen in patients taking [TB402 trade name].

Side effects that may affect more than 1 in 100 people:

- Abnormal number of platelets
- High number of white blood cells
- Low red blood cells
- Swollen lymph nodes
- Infection of eye membrane (conjunctivitis)
- Diarrhoea
- Indigestion
- Nausea
- Stomach pain
- Vomiting
- Fever
- High liver function tests, e.g., elevated ALT, elevated AST
- Allergic reaction
- Blood urea increased
- Decreased appetite
- Joint pain
- Back pain
- Dizziness
- Headache
- Cough
- Coughing up blood
- Excessive sweating
- Itching
- Rash

Side effects that may affect fewer than 1 patient in 100:

- Abnormal blood clotting
- Bleeding outside of blood vessels (haematoma purpura)
- Low white blood cells
- Fainting
- Inflammation of tissue surrounding the heart (pericarditis)
- Low blood pressure on standing
- Palpitations
- Constipation
- Dry mouth
- Enlarged salivary glands
- Inflammation of digestive system
- Inflammation or irritation of the passage between mouth and stomach (oesophagitis)
- Pancreatitis
- Chest pain
- Chills

- Facial swelling caused by fluid retention
- Feeling jittery
- Feeling of tiredness
- Feeling of weakness
- Enlarged liver
- Hepatitis
- Increased bilirubin
- Jaundice (yellowing of eyes, skin)
- Sore throat (pharyngitis)
- Vaginal yeast infections and other fungal infections
- Viral infection
- Alkaline phosphatase increased
- Elevated blood glucose
- Elevated blood lipids
- Elevated potassium in the blood
- Gout
- Damaged muscle tissue (rhabdomyolysis)
- Inflamed muscles
- Muscle pain
- Fits (convulsion)
- Impaired voice
- Problems with nerves that cause numbness or muscle weakness
- Sleepiness
- Tingling sensation
- Miscarriage
- Anxiety
- Confusion
- Depression
- Disorientation
- Suicidal thoughts
- Elevated urea, creatinine in the blood
- Inflamed vagina
- Itchy vagina
- Other vagina discharge
- Vaginal bleeding
- 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
- 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]

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

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

Do not use this medicine after the expiry date stated on the bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or 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 and 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
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Santacruz (East), Mumbai Maharashtra 400 055
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Manufacturer

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

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