

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB398 trade name][†]
Rifapentine

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 [TB398 trade name] is and what it is used for
2. What you need to know before you take [TB398 trade name]
3. How to take [TB398 trade name]
4. Possible side effects
5. How to store [TB398 trade name]
6. Contents of the pack and other information

1. What [TB398 trade name] is and what it is used for

[TB398 trade name] is a medicine used for the initial treatment of tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. [TB398 trade name] is always given together with other medicines to treat tuberculosis. Your healthcare provider has chosen the combination that is right for your condition.

[TB398 trade name] is also used with other medicines for preventing tuberculosis (TB) if you are at high risk of infection.

[TB398 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 [TB398 trade name]

Do not take [TB398 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 ever had liver damage or other severe side effects such as drug fever or chills from taking rifapentine.
- you are currently taking certain medicines: saquinavir, ritonavir, elvitegravir/cobicistat, rilpivirine, etravirine, doravirine, artemisinin and its derivatives or any direct-acting antiviral for chronic hepatitis C. You may develop liver problems if you also take rifapentine.

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

Warnings and precautions

Talk to your health care provider before taking [TB398 trade name] if you:

- have or have ever had problems with your liver as this medicine can affect the way your liver works
- have a rare blood problem called porphyria
- are underweight or malnourished
- are elderly
- your symptoms of tuberculosis return or get worse (see section 4 Possible side effects)
- wear contact lenses. Taking [TB398 trade name] may permanently stain soft contact lenses
- are vitamin K deficient or have hypoprothrombinemia. [TB398 trade name] may cause vitamin K dependent coagulation and severe bleeding. Monitoring of occurrence of coagulation is recommended for patients at particular bleeding risk.

If you are not sure if any of the above apply to you, talk to your healthcare provider before taking [TB398 trade name].

Your health care provider will carry out regular checks of your liver, including blood tests, before and during treatment. Tell your health care provider right away if you develop signs of liver problems such as pain in the upper part of your belly, yellowing of your skin or the whites of your eyes.

Blood tests

It is possible that [TB398 trade name] may interfere with some blood tests. If you need a blood test to check bilirubin, folate or vitamin B12 levels tell your health care provider you are taking [TB398 trade name] as it may affect your results.

Other medicines and [TB398 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including herbal medicines. This is because [TB398 trade name] can affect the way some other medicines work. Also, some medicines can affect the way [TB398 trade name] works.

The following medicines can make [TB398 trade name] work less well:

- Antacids used for indigestion. Take [TB398 trade name] at least 1 hour before taking antacids.
- Other medicines used for TB such as p-aminosalicylic acid (PAS). PAS and [TB398 trade name] should be taken at least 8 hours apart.

Tell your doctor if you are taking any of the following medicines:

Heart and blood medicines

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

Mental health, epilepsy and motor neurone medicines

- Medicines for thought disorders known as 'antipsychotics' such as haloperidol, clozapine
- Medicines to calm or reduce anxiety (hypnotics, anxiolytics) such as diazepam, midazolam, nitrazepam
- Medicines to help you sleep such as zolpidem, zopiclone
- Medicines used for epilepsy such as phenytoin, lamotrigine, phenobarbital, carbamazepine
- Some medicines used for depression such as amitriptyline, nortriptyline
- Riluzole - used for motor neurone disease

Medicines for infections and the immune system

- Some medicines used for HIV or hepatitis infections such as indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, etravirine, rilpivirine, elvitegravir, daclatasvir, simeprevir, sofosbuvir and telaprevir

- Medicines used for fungal infections such as fluconazole, ketoconazole, itraconazole
- Medicines used for bacterial infections (antibiotics) such as chloramphenicol, clarithromycin, dapsone, doxycycline, ciprofloxacin, levofloxacin
- Medicines used for lowering your immune system such as cyclosporine, sirolimus and tacrolimus
- Praziquantel - used for tapeworm infections
- Atovaquone - used for pneumonia
- Artemisinin, artemether, artesunate, chloroquine, lumefantrine, quinine- used for malaria

Hormone and cancer medicines

- Some hormone medicines (estrogen, systemic hormones, progestogens) used for contraception or some types of cancer such as ethinylloestradiol, levonorgestrel
- Some hormone medicines (anti-estrogens) used for breast cancer or endometriosis such as tamoxifen, toremifene and gestrinone
- Some medicines used for cancer (cytotoxics) such as imatinib
- Levothyroxine (thyroid hormone) used for thyroid problems
- Irinotecan - used for cancer

Pain, inflammation and gout medicines

- Medicines used for pain such as codeine, morphine, fentanyl or pethidine
- Corticosteroids used for inflammation such as prednisolone
- Methadone - used for heroin withdrawal

Other medicines

- Medicines used for diabetes such as glibenclamide, glimepiride
- Some medicines used for feeling sick or being sick such as ondansetron
- Theophylline - used for wheezing or difficulty in breathing
- Sildenafil- used to treat male sexual erection problems

Pregnancy and breastfeeding

Tell your healthcare provider if you are pregnant or planning to become pregnant. It is important that your tuberculosis is properly treated during any pregnancy as it can affect the health of both you and your unborn baby.

[TB398 trade name] might affect the growth of your unborn baby during early pregnancy and may increase the risk of bleeding in mother and baby after birth. Your health care provider will discuss the options with you.

If you are able to get pregnant, you should use a reliable barrier method of contraception such as condoms or the “coil” while taking [TB398 trade name]. [TB398 trade name] may make the contraceptive “pill” work less well. This means you should change to a different type of contraception. If you have any questions or are unsure about this talk to your health care provider.

It is not known if [TB398 trade name] passes into breast milk and could affect your baby. As a precaution, you should not breastfeed while taking [TB398 trade name]. If you are breastfeeding or planning to breastfeed, talk to your health care provider.

Driving and using machines

You may feel dizzy while taking [TB398 trade name]. If this happens, do not drive or use any tools or machines.

3. How to take [TB398 trade name]

Always take [TB398 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 [TB398 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 [TB398 trade name] is 4 tablets once **daily**. When used for treatment in this way, [TB398 trade name] is only suitable for people aged 12 years or older. It is taken together with other tuberculosis medicines.

Prevention of tuberculosis

For prevention of tuberculosis, [TB398 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:

Patient's weight	Number of tablets
10 to less than 16 kg	1
16 to less than 24 kg	1½
24 to less than 31 kg	2
31 kg and over	2½

For *patients aged over 14 years* and weighing at least 30 kg the usual recommended dose is 3 tablets of [TB398 trade name] weekly with isoniazid for 3 months.

In some cases, your health care provider may recommend a shorter preventive treatment, where [TB398 trade name] is given in a recommended dose of 2 tablets **daily**, together with isoniazid, for one month.

Always take [TB398 trade name] as your health care provider advises and ask them if you are not sure how to take your tablets.

If you take more [TB398 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 [TB398 trade name]

It is important that you take 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 [TB398 trade name], the dose should be repeated.

If you stop taking [TB398 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, [TB398 trade name] can cause side effects, although not everybody gets them.

The table below shows side effects of [TB398 trade name] that are common and very common (seen in at least 1 patient in 100) and those that are uncommon, rare and very rare (seen in less than 1 patient in 100).

Side effect	May occur in at least 1 patient in 100	May occur in less than 1 patient in 100
Infections and infestations	Influenza Shingles (herpes zoster)	Fungal infections Parasitic infections Protozoal infection
Cancer and abnormal growths		Lung cancer Other cancers (carcinoma) Non-cancerous tumour formed by fat cells (lipoma)
Blood and lymph problems	Low red blood cells Low white blood cells Abnormal number of platelets Swollen lymph nodes	Excessive white blood cells Bleeding outside of blood vessels (haematoma, purpura) Abnormal red blood cells Blood clots
Metabolism and nutritional problems	Elevated uric acid levels in the blood Elevated potassium levels in the blood Low blood glucose Elevated blood glucose Elevated blood cholesterol Elevated blood phosphates	Weight changes Increased blood urea (measure of kidney function) Diabetes mellitus High liver function tests, e.g., increased alkaline phosphatase Low phosphate levels in blood Elevated calcium levels in blood Decreased fluid in blood vessels
Mental problems	Loss of appetite Difficulty sleeping	Anxiety Confusion Drug abuse Aggressive reaction Agitation
Brain and nerve problems	Headache Dizziness Tremor	Drowsiness, stupor Seizures Hoarse voice Numbness Stiff neck Excessive muscle tone causing limb stiffness Decreased muscle reflexes Inflammation of tissue surrounding brain (meningitis) Migraine headache
Eye problems	Infection of eye membrane (conjunctivitis)	Eye pain, eye abnormality
Ear and balance problems		Inflammation of inner or middle ear Earache Perforated ear drum
Blood vessel and heart problems	High blood pressure	Fainting Palpitations Low blood pressure on standing Inflammation of tissue surrounding the heart (pericarditis) Inflammation of veins Problems with blood vessels, e.g., widening of

		blood vessels with flushing and dizziness
Chest, lung and breathing problems	Coughing up blood from the chest Coughing Upper respiratory tract infection Inflamed airways (bronchitis) Sore throat Nosebleed Inflammation of lung tissue (pleuritis)	Abnormal breath sounds Collapsed lung (pneumothorax) Lung infection Fluid accumulation around the lungs Runny nose Shortness of breath Inflammation of lung tissue (pneumonitis) Sinusitis Increased phlegm Scarring of lung tissue Asthma Abnormal chest x-ray Constriction of airways (bronchospasm) Laryngitis
Mouth, stomach and bowel problems	Indigestion Vomiting Nausea Constipation Diarrhoea Haemorrhoids	Problems with teeth Inflammation of digestive system Inflammation of the passage between mouth and stomach Swollen lips Dry mouth Pancreatitis Inflamed anus Salivary gland enlargement Feeling of being unable to empty the bowel Loss of taste
Liver and gall bladder problems	High liver function tests, e.g., increased ALT, increased AST	Increased blood urea Enlarged liver Jaundice (yellowing of eyes, skin)
Skin problems	Rash Sweating Itching Acne Eczema	Ulcers on the skin Hives Dry skin Boils Skin discolouration Fungal infection of skin Hair loss Itchy red rash
Muscle, bone and joint problems	Joint pain Joint inflammation Gout (severe joint pain caused by too much uric acid in the blood)	Muscle pain Muscle weakness and fatigue Muscle spasm Bone fracture
Kidney and bladder problems	Pus in urine Protein in urine Blood in urine Infection of parts of the body that collect and pass out urine Urinary casts Bladder inflammation	Disorders of the urethra Painful urination Kidney infection Lack of control over passing Other urination disorders
Reproductive system and breast problems		Miscarriage Penis disorder Swollen vagina Vaginal bleeding Positive cervical smear test

		Whitish mucus from the vagina Swollen breasts in males Prostate problems
General problems	Red-orange discoloration of body tissues and/or fluids (e.g., skin, teeth, tongue, urine, faeces, saliva, sputum, tears, sweat, and cerebrospinal fluid). Contact lenses or dentures may become permanently stained. Back pain, chest pain, abdominal (belly) pain, fever, fatigue	Abnormal laboratory test Leg, arm or facial swelling caused by fluid retention Feeling of weakness Pocket of pus (abscess) General feeling of unwellness

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 [TB398 trade name]

Do not store above 30°C. Protect from excessive heat and humidity. Avoid excursions above 30°C.

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

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

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 [TB398 trade name] contains

- The active ingredient is rifapentine. Each film-coated tablet contains 300 mg rifapentine.
- The other ingredients of [TB398 trade name] are:
Core tablet: microcrystalline cellulose, pregelatinised starch, low-substituted hydroxypropyl cellulose, sodium starch glycolate, sodium lauryl sulfate, hydroxypropyl cellulose, disodium edetate, sodium ascorbate, colloidal silicon dioxide and calcium stearate;
Film coating: polyvinyl alcohol-partially hydrolysed, macrogol/ polyethylene glycol, titanium dioxide, talc and iron oxide red.

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

What [TB398 trade name] looks like and contents of the pack

Reddish-brown, round, film-coated tablets. They are biconvex (rounded on top and bottom) with a bevelled edge. The tablets have a break line on one side with “J” debossed (stamped into the tablet) above the break line and “37” debossed below; they are plain on the other side. The tablet can be divided into equal halves.

[TB398 trade name] is available in Alu/Alu strips. Each strip contains 10 tablets. Such 10 strips are packed in a carton. Pack size: 10 x 10 tablets.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>