

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.

Information for the patient

[TB332 trade name][†]
Rifampicin

*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 [TB332 trade name] is and what it is used for
2. What you need to know before you take [TB332 trade name]
3. How to take [TB332 trade name]
4. Possible side effects
5. How to store [TB332 trade name]
6. Contents of the pack and other information

1. What [TB332 trade name] is and what it is used for

[TB332 trade name] is a medicine containing the active ingredient rifampicin. Rifampicin belongs to a group of medicines called rifamycin antibiotics.

[TB332 trade name] is used in combination with other tuberculosis medicines for the treatment of TB, an infection caused by bacteria called *Mycobacterium tuberculosis*. It may also be given to you on its own, or with other medicines for preventing TB, if you are at high risk of infection.

[TB332 trade name] is also used in combination with other medicines to treat leprosy, a condition caused by bacteria called *Mycobacterium leprae*.

2. What you need to know before you take [TB332 trade name]

Do not take [TB332 trade name] if you:

- are allergic (hypersensitive) to rifampicin or the related medicines rifabutin or rifapentin, or to any of the other ingredients of [TB332 trade name] (see section 6, What [TB332 trade name] contains).
- have jaundice, acute liver disease, or severely reduced liver function
- have had liver damage linked to rifampicin before, or severe side effects such as bleeding and purplish rash due to loss of blood platelets, haemolytic anaemia (damage to red blood cells), shortness of breath, lung damage, steep falls in blood pressure, kidney failure, or severe skin reactions
- are using certain medicines (see 'Other medicines and [TB332 trade name]' below).

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

Warnings and precautions

[TB332 trade name] may cause liver disease (hepatitis). Your health care provider will check your liver function before starting treatment and regularly while you are receiving treatment.

You should be attentive to symptoms that might be due to liver damage, such as unexplained loss of appetite, nausea, vomiting, dark urine, yellow discoloration of the skin and eyes (jaundice), persistent tiredness and weakness for more than 3 days and abdominal pain and tenderness. If these occur, you should immediately report this to your health care provider.

You may be at special risk for developing hepatitis

- if you are older than 35 years,
- if you drink alcoholic beverages daily (see “[TB332 trade name] with food and drink”)
- if you already have reduced liver function or long-term liver disease
- if you are a user of injection drugs (e. g. heroin)

If you belong to one of these groups your health care provider will closely check your liver function. You may also get additional checks:

- if you are regularly taking other medicines (see “Other medicines and [TB332 trade name]”),
- if you are pregnant
- if you are living with HIV.

Your health care provider will need to carry out blood tests before starting treatment with [TB332 trade name] and at times during treatment.

If you get flu-like symptoms such as fever, headache, muscle aches etc., you should report this to your health care provider, since [TB332 trade name] may be the cause. You should also tell your health care provider if your TB symptoms start to get worse again. Inform them immediately if you experience sudden worsening of shortness of breath, maybe with a dry cough or fever which does not respond to antibiotics.

If you have kidney problems, diabetes or porphyria, it is important that you inform your health care provider about this, since your health care provider may need to carry out extra checks or adjust your medicines.

If you are taking cortisone or any cortisone-like medicine, you should report this to your health care provider, since the cortisone dose may have to be increased while taking [TB332 trade name].

[TB332 trade name] may cause a reddish orange colour of body fluids such as urine, sputum and tears. This is due to rifampicin, and does not require medical attention. Also, soft contact lenses may become permanently stained due to [TB332 trade name].

[TB332 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 [TB332 trade name]. If you use contraception, discuss it with your health care provider.

It is important that your health care provider knows about all your signs of illness, even when you think they are not related to tuberculosis infection.

Other medicines and [TB332 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of [TB332 trade name], or [TB332 trade name] may affect their action. Side effects of either medicine may become worse or the medicines may become less effective. **It is important that you tell your health care provider about all your medicines, as some medicines should not be taken with [TB332 trade name], and other medicines may need their doses to be changed.**

You should not take [TB332 trade name] with:

- voriconazole (a medicine used to treat fungal infections).
- HIV protease inhibitors (medicines used to treat HIV infection).
- direct acting antivirals for the treatment of chronic Hepatitis C (daclatasvir, ledipasvir, sofosbuvir, velpatasvir).

The active agent in [TB332 trade name] may also affect or be affected by a great number of other medicines, including for instance:

- medicines used to treat HIV infection (e.g. efavirenz, nevirapine, etravirine, rilpivirine, dolutegravir, raltegravir, maraviroc)
- medicines used to treat fungal infections (e.g. ketoconazole, fluconazole, itraconazole)
- antibiotics (e.g. clarithromycin, chloramphenicol, doxycycline)
- medicines used to treat malaria (e.g. amodiaquine, artemisinin, atovaquone, chloroquine, lumefantrine, mefloquine, quinine)
- immunosuppressant medicines (e.g. cyclosporine, tacrolimus)
- medicines used to treat heart conditions (e.g. verapamil, digoxin)
- medicines used to lower cholesterol (e.g. atorvastatin, simvastatin)
- some medicines used to treat diabetes (e.g. glibenclamide)
- oral contraceptive pills
- medicines used to treat epileptic seizures (e.g. phenytoin, carbamazepine, valproate)
- medicines used to help you sleep (benzodiazepines, e.g. diazepam, flurazepam, triazolam, midazolam)
- medicines used for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol, and some medicines for depression such as amitriptyline)
- medicines used for prevention of blood clots (e.g. warfarin)
- medicines used at surgery (e.g. halothane)
- corticosteroids (medicines for the treatment of inflammations and other diseases, such as asthma or rheumatoid arthritis, e.g. prednisolone,)
- medicines used to treat pain (e.g. morphine, paracetamol)
- codeine (medicine to treat cough)
- disulfiram (medicine used for the treatment of chronic alcoholism)
- antacids (used for indigestion and acid stomach)
- herbal medicines

Taking any of these medicines together with [TB332 trade name] may be unsuitable or require dose adjustment. Talk to your health care provider for advice on your medicines.

[TB332 trade name] with food and drink

[TB332 trade name] should be taken on an empty stomach (at least one hour prior to or two hours after a meal).

You should not drink alcohol while taking [TB332 trade name]. This increases the risk of liver damage.

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, tell your health care provider so you can discuss any concerns. Tuberculosis can be particularly dangerous in pregnancy and should be managed with effective treatment. [TB332 trade name] does not pose additional risks to you or your baby.

Rifampicin can pass into breast milk and may affect its colour. No negative effects have been reported in breast-fed-infants whose mothers were given this medicine, and you may breast-feed during treatment with [TB332 trade name]. However, the amount of the medicine in breast milk is very low and is not enough to protect or treat your child.

Driving and using machines

[TB332 trade name] may cause tiredness, dizziness and other side effects on the nervous system. If you get these effects, do not drive or use machinery.

3. How to take [TB332 trade name]

Your health care provider will work out the right dose of [TB332 trade name] for you, based on your age, weight and condition.

For the **treatment** of TB and leprosy, [TB332 trade name] must be used with other medicines. If you are taking [TB332 trade name] to **prevent** TB, then it may be used on its own or with other medicines – your health care provider will explain which.

Always take your medicine exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

Do not change the dose unless your health care provider tells you to. Your treatment may need to go on for many months, but it is important to take the full course of treatment recommended by your health care provider, even if you feel better.

Treatment and prevention of tuberculosis

The dose of [TB332 trade name] is decided based on your age and body weight and is taken once a day. The usual doses are shown below:

Adults and children over 10 years of age

Body weight	Number of capsules
25 kg to less than 30 kg	1 capsule daily
35 kg and over	2 capsules daily*

If you weigh 30 to less than 35 kg your health care provider will recommend a different medicine in order to supply you with a suitable dose.

Children under 10 years of age

Body weight	Number of capsules
15 kg to less than 25 kg	1 capsule daily
25 kg and over	<i>As for adults, above</i>

For children weighing less than 15 kg or who cannot swallow capsules whole, a different medicine will be used, as [TB332 trade name] is not suitable.

Your health care provider will tell you how long you need to continue taking the medicine and which other medicines to take with it.

Treatment of leprosy

For the treatment of leprosy, [TB332 trade name] only needs to be taken once a month. The recommended dose in adults is 2 capsules of [TB332 trade name] taken once a month.

[TB332 trade name] may not be suitable for the treatment of leprosy in children; your health care provider will work out a suitable product and dose.

How to take [TB332 trade name]

[TB332 trade name] should be swallowed with water or another drink.

The capsules should be taken on an empty stomach (at least one hour prior to or two hours after a meal). Try to take [TB332 trade name] at the same time each day.

If you take more [TB332 trade name] than you should

If you accidentally take too many capsules, immediately contact your health care provider or the nearest hospital emergency department. Take the capsule container with you so that you can easily describe what you have taken.

If you have taken too much [TB332 trade name], you may feel or be sick (vomiting), and get other side effects like itching, pain in your belly, headache, and becoming unresponsive or unconscious. You may also get a reddish-orange discolouration of the skin and body fluids, facial swelling, seizures, low blood pressure and effects on your heart.

If you forget to take [TB332 trade name]

It is important not to miss a dose. If you miss or forget to take a dose, the missed dose should be taken as soon as possible, unless it is less than 6 hours till your next dose, in which case skip the missed dose and just take the next regular dose.

Do not take a double dose to make up for a forgotten capsule.

If you vomit less than 1 hour after taking this medicine, take another dose. You do not need to take another dose if you were sick more than 1 hour after taking [TB332 trade name].

If you stop taking [TB332 trade name]

Do not stop taking this medicine without checking with your health care provider. Stopping your capsules too early may no longer protect you from the infection or cause it to come back.

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

Excipients

Rifampicin 300 mg Capsules contains the following agents which may cause allergic reactions:

0.7 mg carmoisine (azorubine), 0.1728 mg sodium methyl parahydroxybenzoate, 0.0192 mg sodium propyl parahydroxybenzoate, 0.28 mg sunset yellow (FD&C yellow #6) and 0.196 mg ponceau 4R (cochineal redA).

4. Possible side effects

Like all medicines, [TB332 trade name] can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to tell if a side effect is caused by [TB332 trade name] or by any other medicines you may be taking at the same time. For this reason, it is important that you inform your health care provider of any change in your health.

The most important adverse effects of rifampicin are liver problems and skin reactions, which in some cases can be severe and life-threatening.

If you get symptoms of liver problems, **tell your health care provider right away**. These include feeling or being sick (nausea or vomiting), feeling tired or weak for 3 or more days in a row, dark coloured urine or pale faeces, yellowing of the whites of your eyes or skin, itching, rash, or upper stomach pain.

You should **also tell your health care provider right away** if you get severe rashes or blistering, ulcers in your mouth, throat, genitals or eyes, fever and flu-like symptoms, bleeding or unusual bruising, severe headache, new or worsening shortness of breath or cough, blood in your urine or changes in how much urine you make.

You may need to stop taking [TB332 trade name] and go to hospital if severe side effects happen.

The following side effects have been reported in patients treated with [TB332 trade name].

Very common side effects

(may affect more than 1 in 10 people):

- fever
- chills

Common side effects

(may affect up to 1 in 10 people):

- yellow, brown, orange or reddish discoloration of body fluids such as urine, sputum, tears, saliva and sweat.
- loss of appetite,
- feeling sick (nausea)
- vomiting
- increased liver enzymes and levels of a substance called bilirubin, as measured in blood samples (see above, "Take special care with [TB332 trade name]"). Usually, liver enzyme increases occur during the first 1-3 months of therapy and return to normal despite continued treatment. When the values rise above a certain level, your health care provider may decide to stop treatment with [TB332 trade name].
- appearance of new TB symptoms despite continuing to take the medicine correctly
- headache
- dizziness
- tiredness
- drowsiness
- reddening of the eyes
- flushing
- itching (with or without rash)
- nettle rash

Uncommon side effects

(may affect up to 1 in 100 people)

- short-term changes in the white blood cell counts (leucopenia)
- damage to red blood cells, possibly leading to fatigue, weakness and shortness of breath
- diarrhoea

Rare side effects

(may affect up to 1 in 1000 people)

- problems with coordination, balance and speech (ataxia)
- disturbances of vision
- pus and inflammation of the eye (exudative conjunctivitis)
- disturbances of the menstrual cycle sometimes with loss of all periods (amenorrhoea).

Side effects of which it is not known how often they may occur

- severe bowel infection with watery diarrhoea (pseudomembranous colitis)
- painful rash with reddish-purple spots (thrombocytopenic purpura)
- low levels of blood platelets leading to unusual bruising or bleeding (thrombocytopenia)
- tiny clots inside the blood vessels (disseminated intravascular coagulation)
- severe allergic reactions (anaphylaxis)
- reduced function of the adrenal glands affecting the body's ability to respond to stress
- worsening of symptoms in patients with existing reduced adrenal gland function
- changes in personality and abnormal thoughts (psychotic disorder)
- confusion
- bleeding inside the brain (cerebral haemorrhage)
- drastic fall in blood pressure with cold, clammy skin (shock)
- inflammation of blood vessels (vasculitis)
- breathlessness (dyspnoea)
- wheezing

- inflammation of the lungs (interstitial lung disease)
- stomach pain or discomfort
- damage to the stomach lining (erosive gastritis)
- painful inflammation of the pancreas (pancreatitis)
- tooth discoloration (may be permanent)
- liver damage and inflammation (hepatitis)
- high blood levels of bilirubin
- severe skin reactions with fever or flu-like symptoms, blisters and ulcers in mouth, throat, genitals or eyes
- muscle weakness or damage (myopathy)
- bone pain
- kidney damage (may lead to difficulty in passing urine)
- increased levels of waste product (creatinine) in blood tests, a sign of kidney problems
- excess bleeding of mother or baby after giving birth
- worsening of porphyria
- swelling due to fluid in limbs or face (oedema)
- low blood pressure

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 [TB332 trade name]

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

Store at a temperature not exceeding 25°C, in a dry place, protected from light. Dispense in a tight container.

Blister pack: Store capsules in blisters in the provided carton.

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

Do not use this medicine if you notice a 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 [TB332 trade name] contains

- The active ingredient is rifampicin 300 mg.
- The other ingredients of [TB332 trade name] are excipients:

Capsule fill: microcrystalline cellulose, povidone, maize starch, sodium lauryl sulphate, purified talc and magnesium stearate.

Capsule shell: gelatin, sodium methylparahydroxybenzoate (E219); sodium propyl parahydroxybenzoate (E217); sodium lauryl sulphate; titanium dioxide (E171), sunset yellow/ FD&C Yellow #6 (E110); carmoisine/azorubine (E122); and ponceau 4R/cochineal red A (E124).

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

What [TB332 trade name] looks like and contents of the pack

Blisters

10 capsules packed in clear PVC-Alu blister cards. Such 10 blister cards are packed in a box (carton) along with the patient information leaflet.

Strips

10 capsules packed in Alu-Alu strips. Such 10 strips are packed in a box (carton) along with the patient information leaflet.

Bottle pack

100 capsules packed in a self-sealing LDPE bag, put in a plain triple laminated sachet (LDPE/PET-Alu); the triple laminated sachet is kept in a round, wide mouth, opaque, milky white HDPE container sealed with a tagger and closed with a screw thread cap (HDPE), along with the patient information leaflet.

Supplier and Manufacturer

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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/prequal/medicines/prequalified/finished-pharmaceutical-products>