

Package leaflet: Information for the patient

Rifapentine 150 mg Dispersible Tablets

Rifapentine

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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2. What you need to know before you take Rifapentine 150 mg Dispersible Tablets
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1. What Rifapentine 150 mg Dispersible Tablets is and what it is used for

Rifapentine 150 mg Dispersible Tablets is a prescription medicine used with other anti-tuberculosis (TB) medicines to:

- Treat active tuberculosis disease of the lung in people age 12 years and older.
- Prevent progression of inactive (latent) tuberculosis infection to active tuberculosis disease in people aged 2 years and older.

2. What you need to know before you take Rifapentine 150 mg Dispersible Tablets

Do not take Rifapentine 150 mg Dispersible Tablets

- If you are allergic to rifapentine or any of the other ingredient of this medicine (listed in section 6).
- **Do not** take Rifapentine 150 mg Dispersible Tablets if you are allergic to a group of medicines called rifamycins.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

Rifapentine 150 mg Dispersible Tablets should not be used:

- alone to treat people with active or latent TB
- in people with active TB who had taken the medicines rifampin or isoniazid in the past and did not respond (resistant)
- in people who had been exposed to patients with TB that cannot be treated with isoniazid or rifampin

Children and adolescents

Rifapentine 150 mg Dispersible Tablets is safe and effective in children older than 2 years of age who have inactive (latent TB), but it is not known if this medicine is safe and effective for use in the treatment of active TB in children under 12 years of age.

Before you take Rifapentine 150 mg Dispersible Tablets, tell your doctor if you:

- have active TB disease
- know that you have TB that is resistant to treatment with some medicines
- have HIV infection or taking medicines to treat HIV infection
- have liver problems
- have a condition called porphyria
- are pregnant or planning to become pregnant. It is not known if rifapentine will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if rifapentine passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking rifapentine.

Other medicines and Rifapentine 150 mg Dispersible Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using Rifapentine 150 mg Dispersible Tablets with other medicines may affect each other causing serious side effects. This medicine may affect the way other medicines work, and other medicines may affect how this medicine works. Especially tell your doctor if you take medicines to treat HIV infection or oral contraceptives.

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

3. How to take Rifapentine 150 mg Dispersible Tablets

Active pulmonary tuberculosis

Rifapentine is only recommended for the treatment of active pulmonary tuberculosis caused by drug-susceptible organisms as part of regimens consisting of a 2-month initial phase followed by a 4-month continuation phase.

Rifapentine should not be used in the treatment of active pulmonary tuberculosis caused by rifampin-resistant strains.

Initial phase (2 Months)

Rifapentine Tablets should be administered at a dose of 600 mg twice weekly for two months as directly observed therapy (DOT), with an interval of no less than 3 consecutive days (72 hours) between doses, in combination with other anti-tuberculosis drugs as part of an appropriate regimen which includes daily companion drugs such as isoniazid (INH), ethambutol (EMB) and pyrazinamide (PZA).

Continuation phase (4 Months)

Following the initial phase (2 months), continuation phase (4 months) treatment consists of Rifapentine Tablets 600 mg once-weekly for 4 months in combination with isoniazid or another appropriate anti-tuberculosis agent for susceptible organisms administered as directly observed therapy.

Latent tuberculosis infection

Rifapentine Tablets should be administered once-weekly in combination with isoniazid for 12 weeks (3HP) as directly observed therapy or once daily in combination with isoniazid for 28 days (1HP) as directly observed therapy as below

Regimen	Dose by age and weight band					
Three months of Rifapentine plus high dose isoniazid weekly (12 doses) (3HP)	Age 2 – 14 years					
	Medicine, formulation	10-15 kg	16-23 kg	24-30 kg	31-34 kg	>34 kg
	Rifapentine 150 mg tablet	2	3	4	5	5
	Age >14 years					
	Medicine, formulation	30-35 kg	36-45 kg	46-55 kg	56-70 kg	>70 kg
	Rifapentine 150 mg tablet	6	6	6	6	6
One month of Rifapentine plus isoniazid daily (28 doses) (1HP)	Age ≥ 13 years (regardless of weight band) Rifapentine 600mg/day					

Method of administration

Rifapentine is administered orally and should be taken with meal

The tablets should be dispersed in drinking water before administration of the dose.

The tablet should be dispersed completely in 30 mL of water and administered immediately and then followed by additional 20 mL of water to rinse the cup should then be consumed immediately.

It is important that the patient takes the medicine regularly as prescribed. Missing doses can increase the risk of resistance to rifapentine and reduce its effectiveness.

The duration of therapy is dependent on the therapeutic indication as well as the combination of drugs used together with rifapentine. Official national and/or international guidelines, e.g. of the WHO should be consulted.

If you take more Rifapentine 150 mg Dispersible Tablets than you should

If you take more than the recommended dose of Rifapentine 150 mg Dispersible Tablets you may be at higher risk of side effects of this medicine (see section 4, Possible side effects).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet strip with you so that you can show what you have taken.

Do not stop taking Rifapentine 150 mg Dispersible Tablets

It is important to take all of your Rifapentine 150 mg Dispersible Tablets and your other TB medicines. Do not skip doses.

Skipping doses may cause this medicine to not work as well and may increase the chance that your TB will not be treatable by this medicine or other medicines.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Do not stop taking Rifapentine 150 mg Dispersible Tablets without talking to your doctor. Stopping this medicine can seriously affect how well future treatment works. If Rifapentine 150 mg Dispersible Tablets are stopped for any reason, speak to your doctor before you restart taking this medicine.

When your supply of Rifapentine 150 mg Dispersible Tablets starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The disease may then become harder to treat.

4. Possible side effects

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

Rifapentine 150 mg Dispersible Tablets may cause serious side effects, including:

- **Relapse of your TB symptoms.** Active TB disease may return after improvement (relapse) in some people, especially people who do not take this medicine exactly as their doctor tells them to. It is important that you take this medicine exactly as your doctor tells you to. Your doctor should check you for worsening signs and symptoms of your TB while you take this medicine.
- **change in the normal color of your skin, mouth and body fluids.** Rifapentine 150 mg Dispersible Tablets may cause your skin, teeth, tongue, urine, feces, saliva, sputum, tears, sweat, and breast milk to turn a red-orange color. Contact lenses or dentures may become permanently stained.
- **diarrhea.** A type of diarrhea called *Clostridium difficile*-associated diarrhea (CDAD) may occur during or after taking antibiotics, including this medicine. The severity of CDAD can range from mild diarrhea to severe diarrhea that may cause death (fatal colitis). Tell your doctor right if you have diarrhea while you take or after you stop taking this medicine.
- **worsening of a condition called porphyria.**

The most common side effects of rifapentine include: allergic reactions and flu-like symptoms; abnormalities such as low red blood cells, low white blood cells, coughing up blood, cough, excessive number of platelets in the blood, increased sweating, high liver function tests, back pain, rash, decreased appetite, joint pain, increased blood urea, and headache.

Rifapentine 150 mg Dispersible Tablets may cause serious side effects, including:

- **Liver problems.** Rifapentine 150 mg Dispersible Tablets may cause serious liver problems. Your doctor may do a blood test to check your liver function before and while you take this medicine. Stop taking this medicine and call your doctor right away if you have any of the following signs and symptoms of liver problems:

- nausea
- stomach pain
- tiredness, yellowing skin or whites of your eyes
- vomiting
- loss of appetite
- dark urine

- **Allergic reactions and flu-like symptoms.** Allergic reactions and flu-like symptoms have happened in some people taking Rifapentine 150 mg Dispersible Tablets. 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

Signs and symptoms of a flu-like reaction may include:

- weakness
- nausea and vomiting
- chills
- itching
- shortness of breath
- fainting
- tiredness
- headache
- aches
- sweats
- chest pain
- fast heartbeat
- muscle pain
- fever
- rash
- dizziness
- cough

- **Severe skin reactions.** Serious skin reactions such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome have happened in some people taking PRIFTIN. Stop taking PRIFTIN right away and call your doctor or get emergency help 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

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Rifapentine 150 mg Dispersible Tablets. For more information, ask your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the respective drug regulatory authorities. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rifapentine 150 mg Dispersible Tablets

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 which is stated on the carton and the foil label. The expiry date refers to the last day of that month.

Keep this medicine dry and away from heat.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Rifapentine dispersible tablets contains

The active ingredient is Rifapentine

The other ingredients are Microcrystalline Cellulose, Sodium Starch Glycolate, Maize Starch, Hydroxypropyl Methyl Cellulose, Sodium Ascorbate, Sodium Lauryl Sulfate, Disodium Edetate, Crospovidone, Aspartame, Colloidal Silicon Dioxide, Flavour Trusil Peppermint, Flavour Raspberry and Calcium Stearate

What Rifapentine dispersible tablets look like and contents of the pack

Brick red colored, flat faced beveled edged, mottled, circular uncoated tablet with score line on one side and plain on other side with characteristics odour.

Strip pack: 10's Aluminium Strip / 28's Aluminium strip

10 Tablets / 28 Tablets shall be packed per strip using plain strip aluminium foil as base material and printed strip aluminium foil as a lidding material. Such strip is packed in a carton.

Pack sizes: 10 x 10's tablets & 1 x 28's tablets

Blister pack: 10's ALU-ALU Blister / 12's ALU-ALU Blister

10 Tablets / 12 Tablets shall be packed per blister using cold form Alu-Alu blister foil as base material and thick blister hard tampered heat seal lacquer coated printed Aluminium foil as a lidding material. Such blister is packed in a carton.

Pack sizes: 10 x 10's tablets & 10 x 12's tablets

PVC/PVDC Blister pack: 10's PVC/PVDC Blister

10 Tablets shall be packed per blister using Amber PVC/PVDC as a base material and printed blister Aluminium foil as a lidding material. Such blister is packed in a carton.

Pack sizes: 10 x 10's tablets

To report SUSPECTED ADVERSE REACTIONS dsrcm@lupin.com

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