

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is Rifapentine Tablets 300 mg is and what it is used for
2. Before you take Rifapentine Tablets 300 mg s
3. How to take Rifapentine Tablets 300 mg s
4. Possible side effects
5. How to store Rifapentine Tablets 300 mg s
6. Further information

1. WHAT IS RIFAPENTINE TABLETS 300 MG S AND WHAT IT IS USED FOR

Rifapentine 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 with a body weight of more than 40kg including people with HIV [CD4 count > 100cells/mm³] and diabetes.
- prevent progression of inactive (latent) tuberculosis infection to active tuberculosis disease in people age 2 years and older.

Rifapentine 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).
- patients weighing less than 40kg
- patients with severe TB other than lung TB
- patients under 12 years of age
- pregnant or breastfeeding women
- people with HIV having CD4 count < 100cells/mm³

2. BEFORE YOU TAKE RIFAPENTINE TABLETS 300 MG S

- **Do not** take RIFAPENTINE TABLETS 300 MG S if you are allergic to a group of medicines called rifamycins.

Before taking RIFAPENTINE TABLETS 300 MG S, tell your doctor about all of your medical conditions, including if you:

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- 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.

Tell your doctor about all the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements. Using Rifapentine with other medicines may affect each other causing serious side effects. Rifapentine may affect the way other medicines work, and other medicines may affect how Rifapentine 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 TABLETS 300 MG S

- Take Rifapentine exactly as your doctor tells you to take it.
It is important to take all of your Rifapentine and your other TB medicines. Do not skip doses. Skipping doses may cause Rifapentine to not work as well and may increase the chance that your TB will not be treatable by Rifapentine or other medicines.
 - Take Rifapentine with food.
 - If you cannot swallow Rifapentine Tablets 300 mg s whole, they can be crushed and mixed with small amount of semisolid food. Be sure to take all of the semisolid food with Rifapentine in it right away.
 - The tablet can be divided into equal doses.

The recommended doses of Rifapentine Tablets 300 mg 300mg are as follow:

To treat active tuberculosis disease of the lung: 04 tablets daily along with Isoniazid, Moxifloxacin and Pyrazinamide. It should be taken for period of 04 months

To prevent progression of inactive (latent) tuberculosis infection to active tuberculosis disease:

Dose of Rifapentine once weekly for a period of 12 weeks in combination with Isoniazid (15mg/kg or 25mg/kg) is as follows:

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Weight range	RIFAPENTINE dose	Number of Rifapentine Tablets 300 mg s
10-14 kg	300 mg	2
14.1-25 kg	450 mg	3
25.1-32 kg	600 mg	4
32.1-50 kg	750 mg	5
>50 kg	900 mg	6

4. POSSIBLE SIDE EFFECTS

Rifapentine may cause serious side effects, including

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

Nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing skin or whites of your eyes, dark urine
- Allergic reactions and flu-like symptoms.** Allergic reactions and flu-like symptoms have happened in some people taking Rifapentine. Signs and symptoms of an allergic reaction may include:

low blood pressure (hypotension), difficulty breathing, hives, cough with wheezing, red eyes (conjunctivitis), lower blood platelet levels

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

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

Stop taking Rifapentine right away and call your doctor or get emergency help if you have any of the following symptoms:

Rash, peeling or bleeding skin, swollen face, lips, mouth, tongue or throat, red and painful skin, sores or blisters on the inside of your mouth or lips, flu-like symptoms .
- Relapse of your TB Symptoms.** Active TB disease may return after improvement (relapse) in some people, especially people who do not take Rifapentine exactly as their doctor tells them to. It is important that you take Rifapentine exactly as your doctor tells you to. Your doctor should check you for worsening signs and symptoms of your TB while you take Rifapentine.

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- **Change in the normal color of your skin, mouth and body fluids.** Rifapentine 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 *Clostridioides difficile*-associated diarrhea (CDAD) may occur during or after taking antibiotics, including Rifapentine. The severity of CDAD can range from mild diarrhea to severe diarrhea that may cause death (fatal colitis). Tell your doctor right away if you have diarrhea while you take or after you stop taking Rifapentine.
- **Worsening of a condition called porphyria.**

The most common side effects of Rifapentine include: 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, decreased appetite, joint pain, increased blood urea, and headache.

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. For more information, ask your doctor or pharmacist.

5. HOW TO STORE RIFAPENTINE TABLETS 300 MG S

Do not store above 30°C. Protect from excessive heat and humidity. Avoid excursions above 30°C. Keep out of reach of children.

Do not use Rifapentine Tablets 300 mg s after the expiry date, which is stated on the label, carton, and strip. The expiry date refers to the last day of that month.

General information about the safe and effective use of rifapentine.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Rifapentine for a condition for which it was not prescribed. Do not give Rifapentine to other people, even if they have the same symptoms you have. It may harm them. This Medication Guide summarizes the most important information about Rifapentine. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Rifapentine that is written for healthcare professionals.

6. FURTHER INFORMATION**What Rifapentine Tablets 300 mg s contains**

The active ingredient is Rifapentine.

The other ingredients are:

Core tablet: Microcrystalline Cellulose, Pregelatinized Starch, Low substituted Hydroxy propyl cellulose, Sodium Starch Glycolate, Sodium Lauryl Sulfate, Hydroxypropyl Cellulose, Disodium Edetate, Sodium Ascorbate, Colloidal Silicon Dioxide, Calcium Stearate.

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Film Coat: Opadry® II 85F565338 Brown (Polyvinyl Alcohol, Polyethylene Glycol/ Macrogol, Titanium Dioxide, Talc, Iron Oxide Red)

What Rifapentine Tablets 300 mg s looks like and contents of the pack

Reddish brown colored, round, beveled edge, biconvex, film coated tablets debossed with "J" and "37" separated by break-line on one side and plain on other side.

Rifapentine Tablets 300 mg s will be packed in,

- Strip pack of 10 Tablets such 3 Strips in a carton along with pack insert (3 X 10 tablets).

Supplier

Macleods Pharmaceuticals Ltd.

304, Atlanta Arcade,

Marol Church Road,

Andheri (East)

Mumbai- 400 059,

India

Phone: +91-22-66762800

Fax: +91-22-2925 6599

E-mail: exports@macleodspharma.com

sjadhav@macleodspharma.com

vijay@macleodspharma.com

Manufacturer

Oxalis Labs

Village Theda,

P.O Lodhimajra, Baddi,

Dist. Solan (DT),

Himachal Pradesh 174101.

India