

**Medication Guide
PRIFTIN (prif - tin)
(rifapentine)
Tablets**

Rx Only

Read this Medication Guide before you start taking PRIFTIN and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about PRIFTIN?

PRIFTIN may cause serious side effects, including:

- **Liver problems.** PRIFTIN may cause serious liver problems. Your doctor may do a blood test to check your liver function before and while you take PRIFTIN. Stop taking PRIFTIN 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 PRIFTIN. 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

What is PRIFTIN?

PRIFTIN 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 age 2 years and older.

PRIFTIN 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

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

Who should not take PRIFTIN?

- **Do not** take PRIFTIN if you are allergic to a group of medicines called rifamycins.

What should I tell my doctor before taking PRIFTIN?

Before taking PRIFTIN, tell your doctor about all of your medical conditions, including 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 PRIFTIN will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PRIFTIN passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking PRIFTIN.

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

Using PRIFTIN with other medicines may affect each other causing serious side effects. PRIFTIN may affect the way other medicines work, and other medicines may affect how PRIFTIN 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.

How should I take PRIFTIN?

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

What are possible side effects of PRIFTIN?

PRIFTIN may cause serious side effects, including:

- see "What is the most important information I should know about PRIFTIN?"
- **relapse of your TB symptoms.** Active TB disease may return after improvement (relapse) in some people, especially people who do not take PRIFTIN exactly as their doctor tells them to. It is important that you take PRIFTIN exactly as your doctor tells you to. Your doctor should check you for worsening signs and symptoms of your TB while you take PRIFTIN.
- **change in the normal color of your skin, mouth and body fluids.** PRIFTIN 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 PRIFTIN. 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 PRIFTIN.
- **worsening of a condition called porphyria.**

The most common side effects of PRIFTIN 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.

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 PRIFTIN. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PRIFTIN?

- Store PRIFTIN at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep PRIFTIN dry and away from heat.
- Keep PRIFTIN and all medicines out of reach of children.

General information about the safe and effective use of PRIFTIN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PRIFTIN for a condition for which it was not prescribed. Do not give PRIFTIN 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 PRIFTIN. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about PRIFTIN that is written for healthcare professionals.

What are the ingredients in PRIFTIN?

Active ingredient: rifapentine

Inactive ingredients: calcium stearate, disodium EDTA, FD&C Blue No. 2 aluminum lake, hydroxypropyl cellulose, hypromellose USP, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, propylene glycol, sodium ascorbate, sodium lauryl sulfate, sodium starch glycolate, synthetic red iron oxide, and titanium dioxide

Manufactured by: sanofi-aventis U.S. LLC, Bridgewater, NJ 08807
For more information, go to www.sanofi.us or call 1-800-633-1610, and select option 1.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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