

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### PRIFTIN® 150mg, 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 are 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:**

1. What Priftin is and what it is used for
2. What you need to know before you take Priftin
3. How to take Priftin
4. Possible side effects\_
5. How to store Priftin
6. Content of the pack and other information.

### **1. WHAT PRIFTIN IS AND WHAT IT IS USED FOR**

#### **What Priftin is**

Pharmacotherapeutic group: Anti-infective for systemic use, of the family of antibacterial antibiotics of the antituberculous class - ATC code: J04AB05 (J: Anti-infective).

Priftin is a prescription medicine used with isoniazid medicine to:

- prevent progression of inactive (latent) tuberculosis infection to active tuberculosis disease in people age 2 years and older.

Do not use Priftin:

- alone to treat people with latent TB
- 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).

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRIFTIN**

#### **Contraindications:**

Priftin is contraindicated in patients with a history of hypersensitivity to rifampicins.

#### **Appropriate precautions for use; special warnings:**

##### **Before you take Priftin, tell your doctor if you:**

- know that you have TB
- 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. You and your doctor should decide if you will take Priftin or breastfeed.
- Priftin can 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.
- A type of diarrhea called *Clostridium 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.

## **Other medicines and 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.

### **3. HOW TO TAKE PRIFTIN**

#### **How should I take Priftin?**

- 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.

#### **Dosage**

##### **Latent tuberculosis infection:**

Priftin should be administered in combination with isoniazid once weekly for 12 weeks as directly observed therapy.

Adults and children  $\geq 12$  years: Priftin (based on weight, see table below) and isoniazid 15 mg/kg (900 mg maximum).

Children 2 to 11 years: Priftin (based on weight, see table below) and isoniazid 25 mg/kg (900 mg maximum).

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

The maximum recommended dose of Priftin is 900 mg once weekly for 12 weeks.

#### **Frequency of administration**

Take Priftin exactly as your doctor tells you to take it.

#### **Treatment period**

It is important to take all of your Priftin and your isoniazid. Do not skip doses.

### **4. POSSIBLE SIDE EFFECTS**

**Priftin may cause serious side effects, including:**

#### **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

**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

**Other side effects of Priftin include**

- change in the color of body fluids to orange-red
- decrease in white blood cell and red blood cell count
- decreased appetite
- skin rash or itching
- red eyes
- *Clostridium Difficile*-diarrhea.

**Reporting of side effects**

If you get any side effects, talk to your doctor, your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

**5. HOW TO STORE PRIFTIN**

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Store below +30°C. Protect from excessive heat and humidity.

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

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 protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Priftin contains**

**The active substance is:**

Rifapentine ..... 150 mg

For one tablet.

The other ingredients are:

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.

**What Priftin looks like and contents of the pack**

This medicine is supplied as tablets; box of 24.

**Conditions of prescription and issuance:**

List I

**Marketing Authorization Holder**

Sanofi-aventis U.S. LLC,  
Bridgewater, NJ 08807  
USA

**Manufacturer**

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03012 Anagni  
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