PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRIFTIN 150 mg film-coated tablet

Rifapentine

Sugar free.

Read all of this leaflet carefully before you start taking PRIFTIN:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PRIFTIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PRIFTIN is and what it is used for

The active substance of PRIFTIN is rifapentine. Each film-coated tablet contains 150 mg rifapentine.

PRIFTIN contains rifapentine which belongs to the rifamycin class of antibiotics. It is used with other anti-tuberculosis (TB) medicines to treat inactive (latent) tuberculosis infection and to prevent its progression to active tuberculosis disease in people aged 2 years and older who are at risk. PRIFTIN should not be used in people with active TB.

For the treatment of latent tuberculosis infection PRIFTIN must always be used in combination with the anti-tuberculosis medicine isoniazid.

2. What you need to know before you take PRIFTIN

Do not take PRIFTIN:

- If you are hypersensitive (allergic) to rifapentine or to a group of medicines called rifamycins (e.g. rifampicin and rifabutin), or to any of the ingredients of PRIFTIN.
- If you have a condition called porphyria (a group of disorders that can cause nerve or skin problems (blisters and itching) due to a problem with the production of haem (blood pigment) and red blood cells within the body).
- If you have acute or chronic liver disease.

Warnings and precautions

Take special care with PRIFTIN:

Tell your doctor or health care provider before you are given PRIFTIN tablets:

- If you have liver problems. Your doctor may do a blood test to check your liver function before and while you take PRIFTIN (see Do not take PRIFTIN if).
- If you have active TB disease.
- If you know that you have TB that is resistant to treatment with some medicines.
- If you are pregnant or breastfeeding or if you are planning to become pregnant or to breastfeed (see Pregnancy and breastfeeding).
- If you take medicines to treat HIV infection or take oral contraceptives. Using these

medicines with PRIFTIN may make them less effective (see Other medicines and PRIFTIN).

- If you use a medicine called digoxin (used to make the heart beat stronger and with a more regular rhythm). Your doctor will monitor your dose of digoxin as it could change due to PRIFTIN. Even small changes need to be monitored to prevent serious side effects from occurring (also see Other medicines and PRIFTIN).
- **If you wear contact lenses or dentures. PRIFTIN may change the normal colour of your skin, mouth and body fluids and cause your skin, teeth, tongue, urine, stools, saliva, sputum, tears, sweat, and breast milk to turn a red-orange colour. Contact lenses or dentures may become permanently stained.**

If you experience any of the following after or while you are taking PRIFTIN, tell your doctor or health care provider immediately:

- If you experience symptoms of a hypersensitivity (allergic) reaction after taking PRIFTIN, e.g. low blood pressure, hives, swelling of the face, lips, tongue or throat, difficulty breathing, red eyes or flu-like syndrome (weakness, extreme tiredness, muscle pain, nausea and vomiting, headache, fever, chills, aches, rash, itching, sweats, dizziness, shortness of breath, chest pain, cough, fainting, fast heartbeat). These may be symptoms of a serious allergic reaction and you must immediately stop taking PRIFTIN and go to the casualty department at your nearest hospital (see Possible side effects).
- PRIFTIN may cause serious liver problems. Stop taking PRIFTIN 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 of the skin or whites of your eyes, dark urine (see Possible side effects).
- Severe skin problems such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome have been reported with the use of PRIFTIN.

- SJS symptoms may include blistering, peeling or bleeding on any part of your skin with or without a rash. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.
- DRESS symptoms and signs may include flu-like symptoms and a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia). If you develop any skin reaction, stop treatment immediately and contact your doctor or health care provider.

- PRIFTIN may cause a type of diarrhoea called *Clostridium difficile*-associated diarrhoea (CDAD) which may occur during or after taking PRIFTIN. The severity of CDAD can range from mild diarrhoea to severe diarrhoea that may cause death (fatal colitis). Tell your doctor immediately if you have diarrhoea while you are taking or after you have stopped taking PRIFTIN (see Possible side effects).

Other medicines and PRIFTIN:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- When using PRIFTIN with other medicines, they may affect each other causing serious side effects or causing one of the medicines to be ineffective.
- Before you take PRIFTIN, tell your doctor or health care provider if you are taking or have recently taken any of the medicines mentioned below.
- PRIFTIN may make the following medicines work less well:
  - medicines used to treat HIV infection: indinavir, darunavir, lopinavir, saquinavir, ritonavir, rilpivirine, zidovudine
  - antifungal medicine (to treat fungal infections): itraconazole, ketoconazole, voriconazole
  - pain killers (narcotic analgesics): methadone, alfentanil, buprenorphine

- medicines used for diabetes to lower blood sugar: repaglinide
- medicines to lower blood pressure, called calcium channel blockers: felodipine, diltiazem, verapamil, nifedipine
- medicines to lower blood pressure called alpha or beta adrenergic antagonists: alfuzosin, propranolol
- medicines to treat migraine, sometimes referred to as ergot alkaloid derivates: ergotamine
- medicines used to prevent the blood from clotting (anticoagulants): warfarin
- hormonal contraceptives for women. If you are using any form of contraception, such as contraceptive tablets, transdermal patches (patches used on the skin) or an implant while taking PRIFTIN tablets, you should discuss the need to use an additional non-hormonal means of contraception or to change your contraceptive pill with your doctor or health care provider to make sure that your method of contraception is still effective
- medicines used to lower your immune system: ciclosporin, tacrolimus, sirolimus
- medicines used as sedatives or to treat anxiety: midazolam.

Other medicines which could be affected by PRIFTIN:

- Digoxin (used to make the heart beat stronger and with a more regular rhythm). Your doctor will monitor your dose of digoxin as it could change due to PRIFTIN. Even small changes need to be monitored to prevent serious side effects from occurring (see Take special care with PRIFTIN).
- Medicines used for inflammation (e.g. ibuprofen, diclofenac).
- Medicines used to lower blood sugar in diabetes: glipizide.

PRIFTIN may also interact with the laboratory tests to determine folate and vitamin B_{12} in your blood. Make sure that you inform your doctor or health care provider that you are using PRIFTIN before such tests are performed.

PRIFTIN with food and drink

Take PRIFTIN and isoniazid tablets with food.

Pregnancy and breastfeeding:

Safety of PRIFTIN during pregnancy and breastfeeding has not been established. You should not be treated with PRIFTIN if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice, before taking this medicine.

You should not breastfeed your baby if you are on treatment with PRIFTIN.
It is not known if PRIFTIN passes into your breast milk. PRIFTIN may potentially cause discolouration of breast milk, since PRIFTIN causes a red-orange discolouration of body fluids.

Driving and using machines

Do not drive or operate machines if you experience any side effects of PRIFTIN which could adversely affect your ability to drive or use machines.

3. How to take PRIFTIN

Do not share medicines prescribed for you with any other person.

Always take PRIFTIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- PRIFTIN should be taken once-weekly in combination with another anti-TB medicine, isoniazid, for 12 weeks as directly observed therapy (DOT). DOT is a way of helping people during their treatment, e.g. your treatment will be monitored weekly by visiting your local clinic, hospital or nurse and they will make sure that you take your treatment correctly.
- Your doctor will calculate the number of tablets you should take weekly based on your weight. This dose will therefore be calculated for you personally.
- It is important to take all of your PRIFTIN and your other TB medicine (isoniazid). 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 and isoniazid with food. This may help prevent nausea, vomiting or stomach upsets due to the medication.
- It is preferable to take antacids at least 1 hour before or 2 hours after your dose of PRIFTIN tablets.
- If you cannot swallow PRIFTIN tablets whole, they can be crushed and mixed with a small amount of semisolid food. Be sure to take all of the semisolid food with PRIFTIN in it immediately.

If you take more PRIFTIN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Always take the labelled medicine package with you, whether there are any PRIFTIN tablets left or not.

If you forget to take PRIFTIN:

Since your weekly dose of PRIFTIN will be given to you via directly observed therapy (DOT) which includes a visit to, for example, your local clinic or hospital, it is unlikely that you will forget to take a dose. However, if you have missed the visit to your local clinic or hospital, visit them as soon as possible and do not skip the whole week until the next appointment.

4. Possible side effects

PRIFTIN can have side effects.

Not all side effects reported for PRIFTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRIFTIN, please consult your health care provider for advice.

If any of the following happens, stop taking PRIFTIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

Frequent:

- Hypersensitivity (allergic) reaction: this may present as a sudden life-threatening allergic reaction and the signs may include low blood pressure, hives, swelling of the face, lips, tongue or throat, difficulty breathing, red eyes or flu-like syndrome (see below).

Less frequent:

- Flu-like syndrome (weakness, extreme tiredness, muscle pain, nausea and vomiting,
- headache, fever, chills, aches, rash, itching, sweats, dizziness, shortness of breath, chest pain, cough, fainting, fast heartbeat) (see Take special care with PRIFTIN).
- Hepatitis (inflammation of the liver) and liver problems (symptoms may include: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of the skin or whites of your eyes, dark urine) (see Take special care with PRIFTIN).

- Diarrhoea called *Clostridium difficile*-associated diarrhoea (CDAD) which may occur during or after taking PRIFTIN. The severity of CDAD can range from mild diarrhoea to severe diarrhoea that may cause death (fatal colitis (see Take special care with PRIFTIN).
- Pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate)
- Pneumonia (infection of the lungs; symptoms may include fever and chills, cough, difficulty breathing, shortness of breath when you climb stairs).

These are all very serious side effects. If you have them, you may have had a serious reaction to PRIFTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent:

- influenza (flu)
- upper abdominal pain
- skin reaction
- pain in one or more muscles (myalgia)
- chills
- fever
- abnormal physical weakness or lack of energy (asthenia).

Frequency unknown:

- SJS including the following symptoms: blistering, peeling or bleeding on any part of your skin with or without a rash (including your lips, eyes, mouth, nose, genitals, hands or feet), flu-like symptoms (fever, chills or aching muscles).

- DRESS including the following symptoms: flu-like symptoms, a widespread rash with a high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent:

- headache
- fatigue or extreme tiredness
- irritation of the oesophagus (the tube that carries food from your throat down to your stomach).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

5. How to store PRIFTIN

- Store at or below 30 °C.
- Protect from excessive heat and humidity.
- Do not expose the tablets to direct sunlight and do not remove the tablets from the blister

strips until ready for use in order to protect them from excessive heat and moisture.

- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What PRIFTIN contains

The active substance of PRIFTIN is rifapentine. Each film-coated tablet contains 150 mg rifapentine.

The other ingredients are:

Calcium stearate, microcrystalline cellulose, pregelatinised starch, sodium ascorbate, sodium lauryl sulphate and sodium starch glycolate.

Tablet film-coat: disodium edetate, hydroxypropyl cellulose, hypromellose, indigo carmine (FD&C Blue No. 2 aluminium lake), polyethylene glycol, propylene glycol, red iron oxide, sodium ascorbate and titanium dioxide.

What PRIFTIN looks like and contents of the pack

Round, dark pink, convex, engraved, film-coated tablets.

24 tablets packed in grey aluminium formable foil blister strips (3 blister strips x 8 tablets) in cardboard cartons.

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd

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South Africa

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Signed:

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