

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

FRIPNIT 300 mg film coated tablet

Rifapentine

FRIPNIT is sugar free.

Read all of this leaflet carefully before you start taking FRIPNIT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FRIPNIT 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 FRIPNIT is and what it is used for
2. What you need to know before you use FRIPNIT
3. How to use FRIPNIT
4. Possible side effects
5. How to store FRIPNIT
6. Contents of the pack and other information



APPROVED PATIENT INFORMATION LEAFLET

1. What FRIPNIT is and what it is used for

FRIPNIT contains rifapentine which belongs to the rifamycin class of antibiotics.

FRIPNIT is used with other anti-tuberculosis (TB) medicines such as isoniazid 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.

FRIPNIT should not be used in people with active TB.

2. What you need to know before you take FRIPNIT

Do not take FRIPNIT:

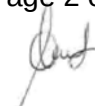
- if you are hypersensitive (allergic) to rifapentine, to a group of medicines called rifamycins (e.g. rifampicin and rifabutin), or to any of the ingredients of FRIPNIT (see section 6)
- if you have a condition called porphyria (a group of disorders that can cause nerve or skin problems (blisters and itching) due to a problem with the production of blood pigment and red blood cells within the body)
- if you have acute or chronic liver disease.

Warnings and precautions

Take special care with FRIPNIT:

Before you are given FRIPNIT tablets tell your doctor or health care provider if you:

- have liver problems. Your doctor may do a blood test to check your liver function before and during your treatment (see Do not take FRIPNIT)
- have active TB disease

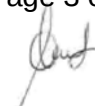


APPROVED PATIENT INFORMATION LEAFLET

- take medicines to treat HIV infection or take oral contraceptives as taking these medicines with FRIPNIT may make them less effective (see Other medicines and FRIPNIT)
- use a medicine called digoxin (used to make the heart beat stronger and with a more regular rhythm). Your doctor will monitor and may change your dose of digoxin as FRIPNIT may affect the way digoxin works. Even small changes need to be monitored to prevent serious side effects from occurring (also see Other medicines and FRIPNIT)
- are pregnant or breastfeeding your baby, or if you are planning to become pregnant or to breastfeed (see Pregnancy and breastfeeding)
- wear contact lenses or dentures. FRIPNIT 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.**

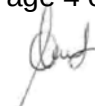
If you experience any of the following effects whilst, or after, taking FRIPNIT, tell your doctor or health care provider immediately:

- if you experience symptoms of hypersensitivity (allergic reaction) after taking FRIPNIT, such as 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 FRIPNIT and go to the casualty department at your nearest hospital (see Possible side effects)



APPROVED PATIENT INFORMATION LEAFLET

- FRIPNIT may cause serious liver problems. If you experience any signs and symptoms of liver problems (such as nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of the skin or whites of your eyes, dark urine) stop taking FRIPNIT and call your doctor immediately (see Possible side effects)
- the following severe skin problems syndrome have been reported with the use of FRIPNIT. If you develop any skin reaction, stop treatment immediately and contact your doctor or health care provider:
 - o Stevens-Johnson syndrome (SJS) with symptoms that 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
 - o drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome with symptoms that 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)
- FRIPNIT may cause a type of diarrhoea called *Clostridium difficile*-associated diarrhoea (CDAD) which may occur either during or after treatment. The severity of CDAD can range from mild diarrhoea to severe diarrhoea that may cause death (fatal colitis). Tell your doctor immediately if you experience diarrhoea either whilst, or after you have stopped taking FRIPNIT (see Possible side effects).



APPROVED PATIENT INFORMATION LEAFLET

Other medicines and FRIPNIT

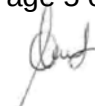
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

When taking FRIPNIT with other medicines, those taken together may affect each other, which may either result in serious side effects or cause one of the medicines to be ineffective.

Before starting therapy with FRIPNIT, tell your doctor or health care provider if you are taking or have recently taken any of the following:

Medicines that may not work as well as expected when taken with FRIPNIT:

- medicines used to treat HIV infection such as indinavir, darunavir, lopinavir, saquinavir, ritonavir, rilpivirine, zidovudine
- antifungal medicines (to treat fungal infections) such as itraconazole, ketoconazole, voriconazole
- pain killers (narcotic analgesics) such as methadone, alfentanil, buprenorphine
- medicines used for diabetes to lower blood sugar such as repaglinide
- medicines to lower blood pressure, called calcium channel blockers such as felodipine, diltiazem, verapamil, nifedipine
- medicines to lower blood pressure called alpha or beta adrenergic antagonists such as alfuzosin, propranolol
- medicines to treat migraine, sometimes referred to as ergot alkaloid derivatives such as ergotamine
- medicines used to prevent the blood from clotting (anticoagulants) such as warfarin
- hormonal contraceptives for women. If you are using any form of contraception, such



APPROVED PATIENT INFORMATION LEAFLET

as contraceptive tablets, transdermal patches (patches used on the skin) or an implant while taking FRIPNIT, you should discuss with your doctor, or health care provider, the need to either use an additional non-hormonal means of contraception, or to change your contraceptive pill in order to ensure your method of contraception is still effective

- medicines used to lower your immune system (used to prevent organ rejection) such as ciclosporin, tacrolimus, sirolimus
- medicines used as sedatives or to treat anxiety such as midazolam.

Other medicines which could be affected by FRIPNIT:

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

FRIPNIT may also interact with the laboratory tests that determine folate and vitamin B12 in your blood. Make sure that you inform your doctor or health care provider that you are taking FRIPNIT before such tests are performed.



APPROVED PATIENT INFORMATION LEAFLET

FRIPNIT with food and drink

FRIPNIT should be taken with food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using FRIPNIT.

The safety of FRIPNIT during pregnancy and breastfeeding has not been established. You should not be treated with FRIPNIT if you are pregnant.

You should not breastfeed your baby if you are taking FRIPNIT as it is not known if FRIPNIT passes into your breast milk.

FRIPNIT may cause a red-orange discolouration of body fluids, including breast milk.

Driving and using machines:

It is not always possible to predict to what extent FRIPNIT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FRIPNIT affects them.



APPROVED PATIENT INFORMATION LEAFLET

3. How to take FRIPNIT

Do not share medicines prescribed for you with any other person. Always use FRIPNIT exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

FRIPNIT 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, this means your treatment will be monitored weekly by visiting your local clinic, hospital or nurse so they can make sure 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 FRIPNIT and your other TB medicine (isoniazid) regularly and you do not skip doses. Missing doses may cause FRIPNIT to not work as well and may increase the chance that your TB will not be treatable by FRIPNIT or other medicines.

Take FRIPNIT 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 FRIPNIT tablets.



APPROVED PATIENT INFORMATION LEAFLET

If you cannot swallow tablets whole, they can be crushed and mixed with a small amount of semi-solid food. Be sure to immediately take all of the semisolid food with FRIPNIT crushed into it.

Your doctor will tell you how long your treatment with FRIPNIT will last.

If you have the impression that the effect of FRIPNIT is too strong or too weak, tell your doctor or pharmacist.

If you take more FRIPNIT 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.

If you forget to take FRIPNIT:

Since your weekly dose of FRIPNIT will be given to you via directly observed therapy (DOT), meaning you will visit, 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 for your dose. Do not skip the whole week until the next appointment.

If you stop taking FRIPNIT

If you stop taking FRIPNIT it may increase the chance that your TB will not be treatable by either FRIPNIT or other medicines.



APPROVED PATIENT INFORMATION LEAFLET

4. Possible side effects

FRIPNIT can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FRIPNIT. 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:

- 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 FRIPNIT)
- 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 FRIPNIT)
- diarrhoea called *Clostridium difficile*-associated diarrhoea (CDAD) which may occur during or after taking this medicine. The severity of CDAD can range from mild



APPROVED PATIENT INFORMATION LEAFLET

diarrhoea to severe diarrhoea that may cause death (fatal colitis) (see Take special care with FRIPNIT)

- 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)
- 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) which are symptoms of a serious skin reaction (Steven Johnson Syndrome) which could be fatal
- a serious reaction (DRESS) with 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 side effects:

- influenza (flu)
- headache, upper abdominal pain
- irritation of the oesophagus (the tube that carries food from your throat down to your stomach).
- skin rash/reaction



APPROVED PATIENT INFORMATION LEAFLET

- muscle pain
- fatigue or extreme tiredness, chills, fever, abnormal physical weakness or lack of energy

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of FRIPNIT. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store FRIPNIT

Store all medicines out of reach of children.

Store below 25 °C. Protect from excessive heat and moisture.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).



APPROVED PATIENT INFORMATION LEAFLET

6. Contents of the pack and other information

What FRIPNIT contains

Each FRIPNIT film coated tablet contains 300 mg rifapentine.

The other ingredients are:

Tablet cores:

Calcium stearate, colloidal silicon dioxide, disodium edetate, hydroxypropyl cellulose, microcrystalline cellulose, pregelatinized starch, sodium ascorbate, sodium lauryl sulphate, sodium starch glycolate.

Tablet coating (Opadry Brown 03G565009)

FD&C yellow #6 / sunset yellow FCF aluminium lake, HPMC 2910 / hypromellose, iron oxide red, iron oxide yellow, macrogol 4000 / PEG, propylene glycol, titanium dioxide.

What FRIPNIT looks like and contents of the pack

Brown coloured, circular, biconvex, film coated tablets, score line on one side and plain on other side.

FRIPNIT is available in:

Aluminium strips of either 10, 12 or 14 tablets per blister.

Alu-Alu blister packs of either 10, 12 or 14 tablets per blister.

Blister strips are packed into printed outer carton with a leaflet.

Not all pack sizes may be marketed



RIFAPENTINE 300 mg tablet
Pharma Dynamics (Pty) Ltd

Final: 24 March 2023
Each film coated tablet contains 300 mg rifapentine

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Holder of Certificate of Registration

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