PATIENT INFORMATION LEAFLET
PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets
rifampicin and isoniazid

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 healthcare provider.
- 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 or your child get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet.

What is in this leaflet
1. What Rifampicin/Isoniazid 300mg/150mg film-coated Tablets is and what it is used for
2. What you need to know before you take Rifampicin/Isoniazid 300mg/150mg film-coated Tablets
3. How to take Rifampicin/Isoniazid 300mg/150mg film-coated Tablets
4. Possible side effects
5. How to store Rifampicin/Isoniazid 300mg/150mg film-coated Tablets
6. Contents of the pack and other information

1. WHAT RIFAMPICIN/ISONIAZID 300MG/150MG FILM-COATED TABLETS IS AND WHAT IT IS USED FOR

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets is a combination of two antimycobacterial agents rifampicin and isoniazid. Antimycobacterial agents are divided into three groups: drugs used in tuberculosis, drugs used in leprosy and drugs used for atypical mycobacteria.

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets is indicated for the treatment of tuberculosis in patients weighing above 50kg.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIFAMPICIN/ISONIAZID 300MG/150MG FILM-COATED TABLETS

Do not take Rifampicin/Isoniazid 300mg/150mg film-coated Tablets if you:
- are hypersensitive (allergic) to isoniazid or rifampicin, or any of the other ingredients of Rifampicin/Isoniazid 300mg/150mg film-coated Tablets (see section 6, What Rifampicin/Isoniazid 300mg/150mg film-coated Tablets contains).
- have acute liver disease,
- have drug-induced liver disease,
- have experienced liver damage linked to isoniazid or rifampicin before,
- have experienced severe side effects of isoniazid or rifampicin, such as drug fever or chills,
- if you are using voriconazole (a medicine used to treat fungal infections) or a medicine against HIV infection that belongs to the class of protease inhibitors.

---

1 Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
Warnings and precautions

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may cause liver disease (hepatitis). You should be attentive to symptoms that might be due to liver damage, such as unexplained loss of appetite, nausea, vomiting, dark urine, yellow discoloration of the skin (jaundice), persistent fatigue of greater than three days duration and abdominal pain and tenderness. If these occur, you should immediately report this to your healthcare provider.

You may be at special risk for developing hepatitis
- if you are older than 35 years,
- if you drink alcoholic beverages daily (see “Taking Rifampicin/Isoniazid 300mg/150mg film-coated Tablets with food and drink”)
- if you have a chronic liver disorder
- if you are a user of injection drugs (e.g., heroin)

If you belong to one of these groups your healthcare provider will closely check your liver function.

Furthermore, you will be carefully monitored
- if you use any chronically administered medication concurrently (see “Taking other medicines”),
- if you suffer from tingling in the hands and feet (peripheral neuropathy),
- if you are pregnant
- if you are HIV infected.

If you get flu-like symptoms such as fever, headache, muscle aches etc., you should report this to your healthcare provider, since Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may be the cause.

Tingling in the hands and feet (peripheral neuropathy) is the most common side effect of isoniazid, one of the active agents in Rifampicin/Isoniazid 300mg/150mg film-coated Tablets (see “Possible side effects). You should report any such symptoms to your healthcare provider. A certain vitamin, pyridoxine, should be administered routinely at doses of 10 mg per day during treatment with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets, since it largely reduces the risk of developing neuropathy.

If you are hypersensitive to ethionamide or niacin (nicotinic acid), you should inform your healthcare provider, because you may also be hypersensitive to Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

If you have epilepsy or a history of psychiatric disease, you should report this to your healthcare provider, since it may affect your ability to tolerate Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

If you have kidney problems, diabetes or porphyria, it is important that you inform your healthcare provider about this, since Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may then be unsuitable for you.

If you are taking cortisone or any cortisone-like drug, you should report this to your healthcare provider, since the cortisone dose may have to be increased while taking Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may cause a reddish orange discoloration of body fluids such as urine, sputum and tears. This is due to rifampicin, and does not require medical
attention. Also, contact lenses may become discoloured due to Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may lower the effects of oral contraceptive pills. Therefore a different or additional method of contraception (e.g. condoms, intra-uterine device, pessary) should be used during treatment with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

It is important that your healthcare provider knows about all your signs of illness, even when you think they are not related to tuberculosis infection.

**Taking other medicines**

Tell your healthcare provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Rifampicin/Isoniazid 300mg/150mg film-coated Tablets, or Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.

You should not take Rifampicin/Isoniazid 300mg/150mg film-coated Tablets with:

- voriconazole (a medicine used to treat fungal infections).
- HIV protease inhibitors, (drugs used to treat HIV infection).
- aluminium hydroxide (medicine used to treat diseases related to the gastric acid) or
- disulfiram (medicine used for the treatment of chronic alcoholism).

The active agents in Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may also interact with a great number of other medicines, including for instance:

- Drugs to treat HIV infection (e.g. efavirenz, nevirapine)
- Drugs used to treat fungal infections (e.g. ketoconazole, fluconazole)
- Antibiotics (e.g. clarithromycin)
- Drugs used to treat malaria (e.g. quinine)
- Immunosuppressant drugs (e.g. cyclosporine, tacrolimus)
- Drugs used to treat heart conditions (e.g. verapamil, digoxin)
- Drugs used to treat blood lipids (e.g. simvastatin)
- Some drugs used to treat diabetes (e.g. glibenclamide)
- Oral contraceptive pills
- Medicines used to treat epileptic seizures (e.g. phenytoin, carbamazepine, valproate)
- Medicines used to help you sleep (benzodiazepines, e.g. diazepam, flurazepam, triazolam, midazolam)
- Medicines used for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol)
- Medicines used for prevention of blood clots (clopidogrel, coumarin, warfarin)
- Medicines used in surgery (narcotics, e.g. alfentanil, enflurane)
- theophylline (medicine used for the treatment of asthma)
- corticosteroids (e.g. prednisolone, medicines used for the treatment of inflammations and other diseases, such as asthma or rheumatoid arthritis)
- paracetamol (pain killer)

Taking any of these drugs together with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may require dose adjustment.
Taking Rifampicin/Isoniazid 300mg/150mg film-coated Tablets with food and drink

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets should be taken on an empty stomach (at least one hour prior to or two hours after a meal).

You should not drink alcohol while taking Rifampicin/Isoniazid 300mg/150mg film-coated Tablets. This increases the risk of liver damage.

When taken with cheese or fish (histamine- or tyramine-rich food) Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may cause redness/itching of the skin, hot feeling, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, and/or lightheadedness. If you experience these side effects you should avoid eating cheese and fish while taking this medicine.

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, you must contact your healthcare provider to discuss the potential benefits and risks of the tuberculosis therapy for you and your child.

Isoniazid and rifampicin are excreted into the breast milk of lactating mothers. No negative effects have been reported in breast-fed-infants whose mothers were receiving these drugs. However, drug concentrations in breast milk are so low that you cannot rely upon breast-feeding for adequate tuberculosis prophylaxis or therapy for your child.

Driving and using machines

Rifampicin/Isoniazid 300mg/150mg film-coated Tablets may cause visual disturbances, dizziness and other side effects on the nervous system that can impair one’s ability to drive and to use machines.

3. HOW TO TAKE RIFAMPICIN/ISONIAZID 300MG/150MG FILM-COATED TABLETS

Always take your medicine exactly as your healthcare provider has told you. You should check with your healthcare provider if you are not sure.

Usual dose:

Adults weighing more than 50kg- two tablets daily

Adults weighing less than 50kg and children- This medicine is not recommended for use in patients weighing less than 50kg.

The tablets should be taken together and swallowed whole with water on an empty stomach (at least one hour prior to or two hours after a meal).

If you have a kidney-disease, your healthcare provider may prescribe separate formulations of the component drugs in Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

Your healthcare provider will decide on the duration of treatment that is suitable for you.

If you take more Rifampicin/Isoniazid 300mg/150mg film-coated Tablets than you should

If you accidentally take too many tablets, immediately contact your healthcare provider or the nearest hospital emergency department. Take the tablet container with you so that you can easily describe
what you have taken. If you have taken too much Rifampicin/Isoniazid 300mg/150mg film-coated Tablets, you may develop vomiting, gastrointestinal disturbances, fever, headache, dizziness, slurring of speech, hallucinations and/or visual disturbances. You may also get a reddish-orange discolouration of the skin, facial swelling and itching.

If you forget to take Rifampicin/Isoniazid 300mg/150mg film-coated Tablets

It is important not to miss a dose. If you miss or forget to take a dose, the missed dose should be taken as soon as possible, unless the next regular dose is scheduled within 6 hours. Skip the missed dose if it is almost time for the next regular dose. Do not take a double dose to make up for a forgotten tablet.

If you vomit less than 1 hour after taking this medicine, take another dose. You do not need to take another dose if you were sick more than 1 hour after taking Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

If you stop taking Rifampicin/Isoniazid 300mg/150mg film-coated Tablets

Do not stop taking this medicine without checking with your healthcare provider. Stopping your tablets too early may no longer protect you from the infection or cause it to come back. If you have any further questions on the use of this medicine, ask your healthcare provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rifampicin/Isoniazid 300mg/150mg film-coated Tablets can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Rifampicin/Isoniazid 300mg/150mg film-coated Tablets, and those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform your healthcare provider of any change in your health.

The following side effects have been reported in patients treated with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets:

The most important adverse effects of isoniazid and rifampicin are nerve injuries (see below) and severe and sometimes fatal inflammation of the liver (hepatitis).

Very common side effects

(may affect more than 1 in 10 people):

-sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy).

Your healthcare provider will prescribe a supplementary medicine with a vitamin called pyridoxine, in order to counteract this (see above, “Take special care with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets”).

-increased liver enzymes as measured in blood samples, (see above, “Take special care with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets”). Usually, liver enzyme increases occur during the first 1-3 months of therapy and return to normal despite continued treatment. When the values rise above a certain level your healthcare provider may decide to stop treatment with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets.

-Flushing
**Common side effects**
*(may affect up to 1 in 10 people):*
- reddish discoloration of body fluids such as urine, sputum, tears, saliva and sweat.
- diarrhoea
- stomach pain
- loss of appetite
- feeling sick (nausea)
- vomiting
- skin reactions with rash and/or itching
- disturbances of the menstrual cycle.

**Uncommon side effects**
*(may affect up to 1 in 100 people)*
- inflammation of the liver (hepatitis)
- fits (epileptic seizures)
- headache
- inflammation of the brain
- personality changes and memory impairment.

If you notice signs of illness suggestive of liver damage (see “Take special care with Rifampicin/Isoniazid 300mg/150mg film-coated Tablets”), you should inform your healthcare provider immediately.

**Rare side effects**
*(may affect up to 1 in 1000 people)*
- Inflammation of the stomach lining (gastritis)
- infection of the intestines (bowel infection)
- inflammation of the kidney (nephritis)
- skin sensitivity to light (photosensitivity reactions)
- Inflammation or swelling of the conjunctiva or pinkeye (conjunctivitis).

**Side effects of which it is not known how often they may occur**
- allergic reactions with fever, muscle aches, and cough
- severe skin reactions with fever, blisters and involvement of the mucous membranes or life threatening anaphylactic reactions
- dizziness, drowsiness
- confusion, disorientation, hallucination,
- inflammation of the lungs (pneumonitis)
- inflammation of the optic nerve (optic neuritis)
- build up of acid in the body (metabolic acidosis), increased blood levels of glucose, a vitamin deficiency syndrome called pellagra (with e.g. dementia, loose stools and skin inflammation)
- metallic taste, dry mouth, flatulence, constipation.
- difficulty in passing urine
changes in the white blood cell counts (leucopenia, neutropenia, eosinophilia, agranulocytosis), possibly resulting in an increased risk of infection
- decreased red blood cell counts (anaemia), possibly leading to fatigue, weakness and shortness of breath
- decreased platelet count, which may result in an increased risk of bruising and bleeding

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your healthcare provider as soon as possible.

**Reporting of side effects**
If you get any side effects, talk to your health care provider. 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 RIFAMPICIN/ISONIAZID 300MG/150MG FILM-COATED TABLETS**

Keep this medicine out of the sight and reach of children.

*Bottle pack:*
- Store below 30°C in a dry place. Protect from light.
- Discard 45 days after first opening.

*Blister Pack:*
- Store below 25°C in a dry place. Protect from light.

Do not use Rifampicin/Isoniazid 300mg/150mg film-coated Tablets after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

**What Rifampicin/Isoniazid 300mg/150mg film-coated Tablets contains**
The active ingredients are rifampicin and isoniazid.

Each tablet contains 300mg of rifampicin and 150mg of isoniazid.

The other ingredients are:
Core tablet: Calcium stearate, croscarmellose sodium, crospovidone, microcrystalline cellulose, povidone, shellac (bleached) and sodium lauryl sulphate.

Film-coat: Colour Ponceau 4R lake (Cochineal Red A), diethyl phthalate, hypromellose, propylene glycol, purified talc and titanium dioxide.

**What Rifampicin/Isoniazid 300mg/150mg film-coated Tablets looks like and contents of the pack**
Brown to reddish brown coloured, circular, biconvex, film coated tablet having break-line on one side and plain on other side.
The break-line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

*Bottle pack*
Tablets are packed in a PET/Alu/LDPE triple laminated sachet which is packed in a round,
tagger sealed opaque milky white HDPE container with HDPE closure.
Pack size: 500 or 1000 Tablets

**Blister packs**

The primary packs are blister cards of 10 tablets (comprised of aluminium foil and amber
coloured PVC/PVDC foil). Such 10 blister cards are packed in a carton along with one pack
insert.
Pack size: 10 x10 Tablets

The primary packs are blister cards of 28 tablets (comprised of aluminium foil and amber
colour PVC/PVDC foil). Such 3 or 24 blister cards packed in a carton along with one pack
insert.
Pack size: 3 x28Tablets or 24×28 Tablets

**Supplier**

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059
India.

Tel: +91-22-66762800
Fax: +91-22-28216599

**Manufacturer**

Macleods Pharmaceuticals Limited
Phase II, Unit II, Plot No. 25 – 27,
Survey No. 366
Premier Industrial Estate
Kachigam, Daman – 396210
India.
Telephone: + 91 260 2244337
Fax: + 91 260 2241565

For any information about this medicinal product, please contact the local representative of the
supplier:

**This leaflet was last approved in September 2017**

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
[https://extranet.who.int/prequal](https://extranet.who.int/prequal).