Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, healthcare provider or pharmacist.
- This medicine has been prescribed for you/your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours/those of your child.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your/your child’s doctor, health care provider or pharmacist.

In this leaflet:
1. What Rifampicin and Isoniazid tablets 150/75 mg is and what it is used for
2. Before you take Rifampicin and Isoniazid tablets 150/75 mg
3. How to take Rifampicin and Isoniazid tablets 150/75 mg
4. Possible side effects
5. How to store Rifampicin and Isoniazid tablets 150/75 mg
6. Further information

1. WHAT Rifampicin and Isoniazid tablets 150/75 mg IS AND WHAT IT IS USED FOR

Rifampicin and Isoniazid tablets 150/75 mg is indicated for the treatment of tuberculosis in adults and children weighing above 30 kg.

2. BEFORE YOU TAKE Rifampicin and Isoniazid tablets 150/75 mg

You should not take Rifampicin and Isoniazid tablets 150/75 mg:
- if you are hypersensitive (allergic) to isoniazid or rifampicin, or any of the other ingredients of Isoniazid/Rifampicin 75 mg/150 mg film-coated Tablets (see section 6, What {product name} contains).
- if you have acute liver disease,
- if you have drug-induced liver disease,
- if you have experienced liver damage linked to isoniazid or rifampicin before,
- if you 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.

Take special care with Rifampicin and Isoniazid tablets 150/75 mg:
Rifampicin and Isoniazid tablets 150/75 mg 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 3 days duration and abdominal pain and tenderness. If these occur, you should immediately report this to your doctor.
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 and Isoniazid tablets 150/75 mg 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 doctor 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 doctor, since Rifampicin and Isoniazid tablets 150/75 mg 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 and Isoniazid tablets 150/75 mg (see “Possible side effects). You should report any such symptoms to your doctor or health care provider. A certain vitamin, pyridoxine, should be administered routinely at doses of 10 mg per day during treatment with Rifampicin and Isoniazid tablets 150/75 mg, since it largely reduces the risk of developing neuropathy.

If you are hypersensitive to ethionamide or niacin (nicotinic acid), you should inform your doctor, because you may also be hypersensitive to Rifampicin and Isoniazid tablets 150/75 mg.

If you have epilepsy or a history of psychiatric disease, you should report this to your doctor, since it may affect your ability to tolerate Rifampicin and Isoniazid tablets 150/75 mg.

If you have kidney problems, diabetes or porphyria, it is important that you inform your doctor about this, since Rifampicin and Isoniazid tablets 150/75 mg may then be unsuitable for you.

If you are taking cortisone or any cortisone-like drug, you should report this to your doctor, since the cortisone dose may have to be increased while taking Rifampicin and Isoniazid tablets 150/75 mg.

Rifampicin and Isoniazid tablets 150/75 mg may cause a reddish orange discouloration 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 and Isoniazid tablets 150/75 mg.

Rifampicin and Isoniazid tablets 150/75 mg 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 and Isoniazid tablets 150/75 mg.

It is important that your doctor or health care provider knows about all your symptoms, even when you think they are not related to tuberculosis infection.

Taking other medicines
It is important that you tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Rifampicin and Isoniazid tablets 150/75 mg, or Rifampicin and Isoniazid tablets
150/75 mg 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 and Isoniazid tablets 150/75 mg 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 and Isoniazid tablets 150/75 mg may also interact with a great number of other medicines, including for instance:
- Drugs to treat HIV infection (e.g. efavirenz, nevirapine)
- Drugs to treat fungal infections (e.g. ketoconazole, fluconazole)
- Antibiotics (e.g. clarithromycin)
- Drugs to treat malaria (e.g. quinine)
- Immunosuppressant drugs (e.g. cyclosporine, tacrolimus)
- Drugs to treat heart conditions (e.g. verapamil, digoxin)
- Drugs to treat blood lipids (e.g. simvastatin)
- Some drugs to treat diabetes (e.g. glibenclamide)
- Oral contraceptive pills
- medicines to treat epileptic seizures (e.g. phenytoin, carbamazepine, valproate)
- medicines used to help you sleep (benzodiazepines, e.g. diazepam, flurazepam, triazolam, midazolam)
- medicines for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol)
- medicines for prevention of blood clots (coumarin or indandione derivates, e.g. warfarin)
- medicines used at surgery (narcotics, e.g. alfentanil, enflurane)
- corticosteroids (e.g. prednisolone, medicines 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 and Isoniazid tablets 150/75 mg may be unsuitable or require dose adjustment.

**Taking Rifampicin and Isoniazid tablets 150/75 mg with food and drink**
Rifampicin and Isoniazid tablets 150/75 mg 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 and Isoniazid tablets 150/75 mg. This increases the risk of liver damage.
When taken with cheese or fish (histamine- or tyramine-rich food) Rifampicin and Isoniazid tablets 150/75 mg 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 doctor or health care 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 and Isoniazid tablets 150/75 mg may cause visual disturbances, dizziness and other side effects on the nervous system that can impair your ability to drive and to use machines.

3. HOW TO TAKE Rifampicin and Isoniazid tablets 150/75 mg
Rifampicin and Isoniazid tablets 150/75 mg should always be taken exactly as described by the doctor or health care provider. You should check with your doctor, health care provider or pharmacist if you are not sure.

The dose of Rifampicin and Isoniazid tablets 150/75 mg is decided on the basis of your body weight.
If you weigh 30-39 kg, take 2 tablets daily.
If you weigh 40-54 kg, take 3 tablets daily.
If you weigh 55-70 kg, take 4 tablets daily.
If you weigh above 70 kg, take 5 tablets daily.

Rifampicin and Isoniazid tablets 150/75 mg should be swallowed with water or another drink.
The tablets should be taken on an empty stomach (at least one hour prior to or two hours after a meal).

If you have a kidney-disease, your doctor may prescribe separate formulations of the component drugs in Rifampicin and Isoniazid tablets 150/75 mg.
Rifampicin and Isoniazid tablets 150/75 mg is not recommended for children with a body weight of less than 30 kg.
Your doctor will decide on the duration of treatment that is suitable for you.

If you take more Rifampicin and Isoniazid tablets 150/75 mg than you should
If you take too many 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 discoloration of the skin, facial swelling and itching. Immediately contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Rifampicin and Isoniazid tablets 150/75 mg
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.
You should not take a double dose to make up for forgotten individual doses.
If you stop taking Rifampicin and Isoniazid tablets 150/75 mg
You should keep taking the medicine for as long as your doctor has ordered, even if you are feeling better. If you stop the medicine too soon, the infection may not be completely cured. You should not stop treatment unless your doctor or health care provider says so.

If you have any further questions on the use of this product, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rifampicin and Isoniazid tablets 150/75 mg 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 and Isoniazid tablets 150/75 mg, and those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform the doctor or health care provider of any change in your health.

The following side effects have been reported in patients treated with Rifampicin and Isoniazid tablets 150/75 mg:

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

The most commonly reported side effects (greater than 1 in every 10 patients treated) include sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy). Your doctor will prescribe a supplementary medicine with a vitamin called pyridoxine, in order to counteract this (see above, “Take special care with Rifampicin and Isoniazid tablets 150/75 mg”). Also, increased liver enzymes as measured in blood samples, very commonly occur (see above, “Take special care with Rifampicin and Isoniazid tablets 150/75 mg”). 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 the doctor may decide to stop treatment with Rifampicin and Isoniazid tablets 150/75 mg. Flushing may also occur after ingesting Rifampicin and Isoniazid tablets 150/75 mg.

Commonly (greater than 1 in every 100 patients treated) reported side effects include a reddish discoloration of body fluids such as urine, sputum, tears, saliva and sweat. Further common side effects are diarrhoea, abdominal pain, loss of appetite, nausea and vomiting, as well as skin reactions with rash and/or itching, ocular redness, permanent discoloration of soft contact lenses and disturbances of the menstrual cycle.

Uncommon side effects (greater than 1 in every 1000 patients treated but less than 1 in 100) are inflammation of the liver (hepatitis) epileptic seizures, headache, inflammation of the brain, personality changes and memory impairment. If you notice signs and symptoms suggestive for liver damage (see “Take special care with Rifampicin and Isoniazid tablets 150/75 mg”), you should inform the doctor or health care provider immediately.

Rare side effects (less than 1 in every thousand patients treated) include gastritis, bowel infection, inflammation of the kidney (nephritis), photosensitivity reactions (skin sensitivity to light) and conjunctivitis.

The following side effects have been reported in patients treated with Rifampicin and Isoniazid tablets 150/75 mg. However, frequency estimates for these effects are not available:
- 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
- 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 doctor, health care provider or pharmacist as soon as possible.

5. **HOW TO STORE Rifampicin and Isoniazid tablets 150/75 mg**

Keep out of the reach and sight of children.

Storage conditions for the bottle: Store in a dry place below 25°C and protect from light.
Storage conditions for the blister packs: Store in a dry place below 30°C and protect from light.

Do not use Rifampicin and Isoniazid tablets 150/75 mg after the expiry date which is stated on the
label. 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. **FURTHER INFORMATION**

**What Rifampicin and Isoniazid tablets 150/75 mg contains**

The active ingredients in Rifampicin and Isoniazid tablets 150/75 mg are rifampicin and isoniazid.

The other ingredients are: crospovidone, magnesium stearate, maize starch, pregelatinised starch,
purified talc, and sodium lauryl sulphate, copovidone, hypromellose, iron oxide red, polyethylene
glycol and titanium dioxide.

**What Rifampicin and Isoniazid tablets 150/75 mg looks like and contents of the pack**

Reddish brown, round biconvex, film-coated tablets, plain on both sides.
The tablets should not be divided.

PVC/PE/PVDC blister cards (24x28 or 10x48) sealed with an aluminium foiled lid or sealed PP bags
containing 1000 tablets. The PP bags are packed in a square, white, opaque, tagger sealed HDPE
bottle and closed with a white polypropylene screw cap.

**Supplier**

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This leaflet was last approved in 01/2014. Section 6 updated May 2016.

Detailed information on this medicine is available on the World Health Organization (WHO) web site: http://www.who.int/prequal/