

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets

Important things you need to know about Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets

- It is very important that you take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets exactly as your doctor has told you.
- You must keep taking it until your doctor tells you to stop.
- If you are taking any other medicines, including medicines you have bought from the pharmacy or shop, you must make sure your doctor knows
- Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets makes all of your body fluids an orange or red colour. Do not worry - this is normal and not harmful
- Take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets on an empty stomach. This means at least 30 minutes before food or 2 hours after food
- While you are taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets, you should not eat cheese, skipjack tuna or drink red wine (see 'Taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets with food and drink')
- If you get a temperature, are sick, begin to feel more unwell, lose your appetite or have yellowing of the skin, gums or eyes, you must talk to your doctor straight away

Read all of this leaflet carefully before you or your child 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, healthcare provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

What is in this leaflet:

1. What Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets is and what it is used for
2. Before you take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets
3. How to take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets
4. Possible side effects
5. How to store Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets
6. Contents of the pack and other information

1. WHAT RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE 150/75/275 MG TABLETS IS AND WHAT IT IS USED FOR

Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets contain three different medicines called rifampicin, isoniazid and ethambutol. They both belong to a group of medicines called anti-tuberculous drugs. They work by killing the bacteria that cause tuberculosis.

Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets are used to treat tuberculosis (also known as TB).

2. BEFORE YOU TAKE RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE 150/75/275 MG TABLETS

You should not take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets:

- You are allergic (hypersensitive) to
 - rifampicin
 - isoniazid
 - ethambutol
 - any of the other ingredients of the Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets (see Section 6: Contents of the pack and other information)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have yellowing of the skin and eyes (jaundice)
- If you have sight problems
- You are taking saquinavir or ritonavir for an HIV infection (see 'Taking other medicines' section below)

Problems with your sight

You should have your eyesight checked before taking these tablets, and if you notice any changes to your vision whilst taking these tablets, you should stop taking them and notify your doctor immediately. In the majority cases, any changes to vision will return to normal within a few weeks/months after stopping treatment however, in rare cases, it may take longer for eyesight to recover or the changes may become permanent.

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets

- You have liver problems
- You have any kidney problems and if you are having more than 600mg rifampicin per day
- You have diabetes. Your diabetes may become more difficult to control while taking this medicine
- You have or have ever had gout (pain or swelling in the joints)
- You have epilepsy
- You have or have ever had mental health problems (such as depression or schizophrenia)
- You feel numb or weak in your arms and legs (peripheral neuropathy)
- You have an HIV infection
- You are underweight or malnourished
- You drink alcohol every day or you are an alcoholic
- You inject yourself with drugs

- You are a black or Hispanic woman
- You have a rare blood problem called ‘porphyria’
- Your doctor has told you that your body takes a long time to get rid of some drugs (you have a slow acetylator status)
- You wear contact lenses. Taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets may permanently stain soft contact lenses
- The person taking this medicine is a child
- You are aged 65 years or older

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets.

Blood Tests

Your doctor will need to check your blood before you take this medicine. This will help your doctor know if any changes happen to your blood after taking this medicine. Before treatment with Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets you should have your kidneys checked. If you are aged 35 years or older or if you develop symptoms suggestive of hepatitis (e.g. abdominal pain, fever, loss of appetite) or feel generally unwell, you will also need to have monthly blood tests to check how your liver is working.

Other medicines and Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets can affect the way some other medicines work. Also some medicines can affect the way Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets work.

In particular, do not take this medicine, and tell your doctor, if you are taking:

- Saquinavir or ritonavir used for HIV infection

The following medicines can make Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets work less well:

- Antacids used for indigestion. Take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets at least 1 hour before taking antacids
- Other medicines used for TB such as P-aminosalicylic acid (PAS) and cycloserine. PAS and Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets should be taken at least 8 hours apart

Tell your doctor if you are taking any of the following medicines:

Heart and blood medicines

- Medicines for high blood pressure
- Medicines for heart problems or to control your heartbeat
- Medicines used to thin the blood such as warfarin
- Medicines used to lower cholesterol
- Water tablets (diuretics) such as eplerenone

Mental health, epilepsy and motor neurone medicines

- Medicines for thought disorders known as ‘antipsychotics’ such as haloperidol
- Medicines to calm or reduce anxiety (hypnotics, anxiolytics)
- Medicines to help you sleep (barbiturates)
- Medicines used for epilepsy such as phenytoin and carbamazepine
- Some medicines used for depression such as amitriptyline and nortriptyline
- Riluzole - used for motor neurone disease

Medicines for infections and the immune system

- Some medicines used for an HIV infection such as stavudine and zalcitabine
- Some medicines used for viral infections such as indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir and nevirapine
- Medicines used for fungal infections
- Medicines used for bacterial infections (antibiotics)
- Medicines used for lowering your immune system such as ciclosporin, sirolimus and tacrolimus
- Praziquantel - used for tapeworm infections
- Atovaquone - used for pneumonia

Hormone and cancer medicines

- Some hormone medicines (estrogen, systemic hormones, progestogens) used for contraception or some types of cancer such as ethinyloestradiol, levonorgestrel or dydrogesterone
- Some hormone medicines (anti-estrogens) used for breast cancer or endometriosis such as tamoxifen, toremifene and gestrinone
- Some medicines used for cancer (cytotoxics) such as imatinib
- Levothyroxine (thyroid hormone) used for thyroid problems
- Irinotecan - used for cancer

Pain and inflammation medicines

- Non-steroidal anti-inflammatory drugs (NSAIDs) such as etoricoxib, aspirin and indometacin
- Medicines used for pain such as codeine, morphine, fentanyl or pethidine
- Corticosteroids used for inflammation such as hydrocortisone, betamethasone and prednisolone
- Methadone - used for heroin withdrawal

Other medicines

- Medicines used for diabetes
- Medicines used to relax muscles before surgery (anaesthetics) such as halothane
- Medicines used for erection problems such as tadalafil
- Some medicines used for feeling sick or being sick such as ondansetron and aprepitant
- Quinine - used for malaria
- Theophylline - used for wheezing or difficulty in breathing

Taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets with food and drink

If Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets are taken with the food and drink listed below you may experience headache, sweating, flushing, fast, uneven or forceful heartbeat (palpitations), dizziness, feel lightheaded or faint (due to low blood pressure).

While taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets do not have:

- Cheese
- Skipjack tuna or other tropical fish
- Red wine

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if you are pregnant, plan to get pregnant or think you are pregnant.

Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets may make the contraceptive “pill” work less well. This means you should change to a different type of contraception. Instead, you must use a reliable barrier method of contraception such as condoms or the “coil” while taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets. If you have any questions or are unsure about this talk to your doctor or pharmacist.

You should not breast-feed if you are taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets. This is because small amounts may pass into the mothers’ milk. If you are breast-feeding or planning to breast feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines

You may feel dizzy or faint, numbness or paraesthesia (abnormal sensation like pins and needles) of the furthest parts of your body, disorientation, or have problems with vision or have other side effects that could affect your ability to drive while taking this medicine. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE 150/75/275 MG TABLETS

Always take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets 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.

Keep taking this medicine

- You must take the tablets every day for the whole time the doctor has told you to take

them

- Do not stop and start taking the tablets. This may increase the risk of side effects and your TB will not be treated properly

How to take the tablets

- Take this medicine by mouth
- Swallow the tablets whole, with a drink of water
- Take at least 30 minutes before a meal or 2 hours after a meal.
- Take all your tablets together each day, as a single dose
- Do not give this medicine to children
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

Your doctor may ask you to take Vitamin B6 during treatment with Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets, especially if you are malnourished, elderly or a diabetic.

How much to take

The usual dose is:

Adults and the Elderly weighing less than 50kg

- Between 3 and 6 tablets each day. The amount depends on your body weight
- If you are elderly, your doctor may monitor your treatment more closely

Children

- This medicine is not recommended for use in children less than 6 years.

If you take more Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets than you should

If you take more Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

You may feel sick (nausea), be sick (vomiting), have stomach pain, itching or a headache. You may also feel tired, sleepy, dizzy, light-headed, have blurred or strange visions (hallucinations) and faint or feel faint. Other signs of taking too much include swelling of the face, eyes or eyelids, slurring of speech, difficulty breathing, fast heartbeat, uneven heartbeats, fits and heart attack.

If you forget to take Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten tablets.

Tests

Taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets may affect the results of some blood tests. In particular, tests for folate, vitamin B12 and liver function. If you are going to have a blood test, it is important to tell your doctor that you are taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets.

If you stop taking Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets

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, this medicine can cause side effects, although not everybody gets them.

Stop taking and go to a hospital straight away if you notice any of the following serious side effects:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, wheezing, swelling of your lips, face, throat or tongue, flushed appearance, agitation or an irregular heartbeat
- You get blistering or peeling (inc. following exposure to sunlight), bleeding, scaling or fluid filled patches on any part of your skin. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem
- You bruise more easily than usual. Or you may have a painful rash of dark red spots under the skin which do not go away when you press on them (purpura). This could be because of a serious blood problem
- You have chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine. These could be signs of a serious type of anaemia
- You have blood in your urine or an increase or decrease in amount of urine you produce. You may also get swelling, especially of the legs, ankles or feet. This may be caused by serious kidney problems
- You have a sudden severe headache. This could be a sign of bleeding in the brain
- Shortness of breath, chest pains and wheezing
- Colour blindness, loss of vision or visual acuity
- Thrombocytopenia (which may result in bruising, nosebleeds, pinpoint red spots, prolonged bleeding after injury) and other disorders such as leucopenia and neutropenia
- Disorientation
- Mental confusion, hallucinations
- Generally feeling unwell
- You get confused, sleepy, cold clammy skin, shallow or difficult breathing, a racing heartbeat or your skin is paler than normal. These could be signs of shock
- You get more infections more easily than normal. Signs include fever, sore throat or mouth ulcers. This could be because you have a low number of white blood cells
- You have bleeding from your nose, ear, gums, throat, skin or stomach. Signs may include a feeling of tenderness and swelling in your stomach, purple spots on your skin and black

or tar-like stools

If you experience any of the following side effects contact your doctor as soon as possible:

- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis, frequency not known).
- Severe extensive skin damage (separation of the epidermis and superficial mucous membranes) (toxic epidermal necrolysis, TEN, may affect up to 1 in 1,000 people)
- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome, may affect up to 1 in 1,000 people)
- Yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (hepatitis, may affect up to 1 in 100 people).
- Skin blistering, red/purple rash, fever headache, cough and joint pain (Stevens-Johnson syndrome, SJS).
- Joint inflammation (Gout)

Talk to your doctor straight away if you notice any of the following serious side effects:

- Mental problems with unusual thoughts and strange visions (hallucinations)
- Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'Pseudomembranous colitis'
- Your fits get worse or you start to have fits
- Flu-like symptoms including chills, fever, headache, dizziness and bone pains

Tell your doctor as soon as possible if you have any of the following side effects:

- Water retention (oedema) which may cause swollen face, stomach, arms or legs
- Muscle weakness or pain or loss of muscle reflexes
- Dizziness, feel lightheaded and faint especially when you stand or sit up quickly (due to low blood pressure)
- Swollen fingers, toes or ankles
- Balance problems with dizziness (vertigo)
- Being unable to concentrate, feeling nervous, irritable or depressed
- Feeling very tired and weak or difficulty sleeping (insomnia)
- Unusual skin sensations such as feeling numb, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Short-term memory loss, anxiety, being less alert or responsive
- Blurred or distorted eyesight
- Wasting of muscles or other body tissues
- Weight loss, night sweats and fever. These could be signs of a blood condition called eosinophilia
- Feeling sick or being sick

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer

than a few days:

- Skin flushing or itching
- Irregular periods
- Constipation, diarrhoea, stomach discomfort or dry mouth
- Headache
- Loss of appetite (anorexia)
- Pain or discomfort when passing urine
- Breast enlargement in men
- Increased thirst, going to the toilet more often and feeling tired. Your blood sugar may be high
- Acne
- Inflammation of the blood vessels.

Other side effects you should discuss with your doctor if you are concerned about them

- You notice a discoloration (yellow, brown, orange or red colour) in your teeth, urine, sweat, phlegm (sputum), saliva or tears. This is quite common and you need not worry. However, the colour may permanently stain soft contact lenses. The colour in tears may last for some time after you have stopped having Rifampicin, Isoniazid and Ethambutol Hydrochloride 150/75/275 mg tablets.

Blood tests

- A blood test may show changes in the way the liver is working.
- High levels of uric acid in the blood (hyperuricaemia)

Reporting of side effects

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

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

5. HOW TO STORE RIFAMPICIN, ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE 150/75/275 MG TABLETS

Alu-PVC/PVDC Blister: Do not store above 25°C, protected from excessive humidity. Protect from light.

Alu-Alu Blister: Do not store above 30°C,. Protect from light

6. FURTHER INFORMATION**What Rifampin, Isoniazid, Pyrazinamide and Ethambutol Tablets contains:**

The active ingredients are Rifampin, isoniazid and Ethambutol HCL.

The Excipients are Microcrystalline Cellulose, Pregelatinised Starch, Colloidal Silicone Dioxide, Crosspovidone, Magnesium Stearate, Gelatin and Ascorbic Acid.