Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for your child.

- 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of your child.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets is and what it is used for
2. What you need to know before your child takes Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets
3. How to take Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets
4. Possible side effects
5. How to store Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets
6. Contents of the pack and other information

1. WHAT RIFAMPICIN/ISONIAZID 60MG/60MG DISPERSIBLE TABLETS IS AND WHAT IT IS USED FOR

Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets is indicated for the treatment of tuberculosis in children weighing below 30 kg.

This product is intended for use in children. Safety information on use in adults is also provided.

2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD TAKES RIFAMPICIN/ISONIAZID 60MG/60MG DISPERSIBLE TABLETS

Your child should not take Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets:
- if he/she is hypersensitive (allergic) to isoniazid or rifampicin, or any of the other ingredients of Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets (see section 6, What Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets contains).
- if he/she have acute liver disease,
- if he/she have drug induced liver disease,
- if he/she have experienced liver damage linked to isoniazid or rifampicin before,
- if he/she have experienced severe side effects of isoniazid or rifampicin, such as drug fever or chills. If he/she is using a medicine against HIV infection that belongs to the class of “protease inhibitors”.

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
Warnings and precautions

Rifampicin/Isoniazid 60mg/60mg Dispersible 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 3 days duration and abdominal pain and tenderness. If these occur, you should immediately report this to your child’s doctor.

One may be at special risk for developing hepatitis
- if one is older than 35 years,
- if one drinks alcoholic beverages daily (see “Taking Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets with food and drink”),
- if one has a chronic liver disorder
- if one is a user of injection drugs (e.g. heroin)

If one belongs to one of these groups, a doctor will closely check the liver function.

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

If your child gets flu-like symptoms such as fever, headache, muscle aches etc., you should report this to your child’s doctor, since Rifampicin/Isoniazid 60mg/60mg Dispersible 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 60mg/60mg Dispersible Tablets (see “Possible side effects”). You should report any such symptoms to your child’s doctor or healthcare provider. A certain vitamin, pyridoxine, should be administered routinely at doses of 10 mg per day during treatment with Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets, since it largely reduces the risk of developing neuropathy.

If your child is hypersensitive to ethionamide or niacin (nicotinic acid), you should inform your child’s doctor, because he/she may also be hypersensitive to Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets.

If your child has epilepsy or a history of psychiatric disease, you should report this to your child’s doctor, since it may affect his/her ability to tolerate Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets.

If your child has kidney problems, diabetes or porphyria, it is important that you inform your child’s doctor about this, since Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets may then be unsuitable for him/her.

If your child is taking cortisone or any cortisone-like drug, you should report this to your child’s doctor, since the cortisone dose may have to be increased while taking Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets.
Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets 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 discolored due to Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets.

Rifampicin/Isoniazid 60mg/60mg Dispersible 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 60mg/60mg Dispersible Tablets. It is important that your child’s doctor or healthcare provider knows about all his/her symptoms, even when you think they are not related to tuberculosis infection.

Other medicines and Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets

It is important that you tell your child’s doctor, healthcare 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/Isoniazid 60mg/60mg Dispersible Tablets, or Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.

One should not take Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets with

- 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 60mg/60mg Dispersible Tablets 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)
- theophylline (medicine for the treatment of asthma)
- corticosteroids (e.g. prednisolone, medicines for the treatment of inflammations and other diseases, such as asthma or rheumatoid arthritis)
- acetaminophen, paracetamol (pain killers)

Taking any of these drugs together with Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets may be unsuitable or require dose adjustment.
Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets with food and drink

Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets should be taken on an empty stomach (at least one hour prior to or two hours after a meal).

One should not drink alcohol while taking Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets. This increases the risk of liver damage.

When taken with cheese or fish (histamine- or tyramine-rich food) Rifampicin/Isoniazid 60mg/60mg Dispersible 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 one becomes pregnant, or is planning to become pregnant, a healthcare provider should be contacted to discuss the potential benefits and risks of the tuberculosis therapy for the mother and the 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 one cannot rely upon breast-feeding for adequate tuberculosis prophylaxis or therapy for one’s child.

Driving and using machines

Rifampicin/Isoniazid 60mg/60mg Dispersible 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.

Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets contains aspartame

This medicinal product contains aspartame, which is a source of phenylalanine and may be harmful for people with phenylketonuria.

3. HOW TO TAKE RIFAMPICIN/ISONIAZID 60MG/60MG DISPERSIBLE TABLETS

Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets should always be taken exactly as described by the doctor or healthcare provider. You should check with your doctor, healthcare provider or pharmacist if you are not sure.

Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets is dosed according to the child’s body weight.

For children weighing 5-7 kg, give 1 tablet per day as a single dose.
For children weighing 8-14 kg, give 1 tablet per day as a single dose.
For children weighing 15-20 kg, give 2 tablets per day as a single dose.
For children weighing 21-30 kg, give 2 tablets per day as a single dose.

Disperse the required number of Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets in approximately 50 ml water and make the child drink the entire dispersion. The reconstituted preparation (tablets dispersed in water) should be used within 10 minutes.

The tablets should be taken on an empty stomach (at least one hour prior to or two hours after a meal).
If your child has a kidney disease, your child’s doctor may prescribe separate formulations of the component drugs in Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets.

Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets is not recommended for adults or children with a body weight of more than 30 kg.

Your child’s doctor will decide on the duration of treatment that is suitable for him/her.

**If one takes more Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets than one should**

If one takes too many tablets, one may develop vomiting, gastrointestinal disturbances, fever, headache, dizziness, slurring of speech, hallucinations and/or visual disturbances. One may also get a reddish-orange discoloration of the skin, facial swelling and itching. One should immediately contact a doctor, healthcare provider or the nearest hospital emergency department for further advice.

**If one forgets to take Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets**

If one misses or forgets 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. One should not take a double dose to make up for forgotten individual doses.

**If your child stops taking Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets**

Your child should keep taking the medicine for as long as the doctor has ordered, even if he/she is feeling better. If one stops the medicine too soon, the infection may not be completely cured. One should not stop treatment unless one’s doctor or healthcare provider says so.

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Rifampicin/Isoniazid 60mg/60mg Dispersible 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 60mg/60mg Dispersible 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 the doctor or healthcare provider of any change in your child’s health.

The following side effects have been reported in patients treated with Rifampicin/Isoniazid 60mg/60mg Dispersible 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).

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 vitamin called pyridoxine in order to counteract this (see above, “Take special care with Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets”). Also, increased liver enzymes, as measured in blood samples, very commonly occur (see above, “Take special care with Rifampicin/Isoniazid 60mg/60mg Dispersible 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 the doctor may decide to stop treatment with Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets. Flushing may also occur after ingesting Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets.

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, 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 of liver damage (see “Take special care with Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets”), you should inform your child’s doctor or healthcare 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/Isoniazid 60mg/60mg Dispersible Tablets. 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 child’s doctor, healthcare provider or pharmacist as soon as possible.

5. HOW TO STORE RIFAMPICIN/ISONIAZID 60MG/60MG DISPERSIBLE TABLETS

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

Storage condition for the bottle: Do not store above 30°C. Protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets contains

The active ingredients are 60 mg rifampicin and 60 mg isoniazid.

The other ingredients are: aspartame, bleached shellac, croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, povidone and raspberry flavour (see section 2, “Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets contains aspartame”).
What Rifampicin/Isoniazid 60mg/60mg Dispersible Tablets looks like and contents of the pack

Brick-red mottled capsule shaped, uncoated tablet having break-lines on both sides. The tablet can be divided into equal halves.

Al/PET/LDPE triple laminated bag kept in an HDPE bottle. Pack size: 1000 tablets.
Al/Al strip pack of 10 tablets. Such 3 or 10 strips per box. Pack size: 30 (3x10), 100 (10x10) tablets.
Al/Al strip pack of 3 tablets. Such 28 strips per box. Pack size: 84 (3x28) tablets.
Al/Al strip pack of 6 tablets. Such 14 strips per box. Pack size: 84 (6x14) tablets.
Al/Al strip pack of 14 tablets. Such 6 strips per box. Pack size: 84 (14x6) tablets.
Al/Al strip pack of 28 tablets. Such 3 strips per box. Pack size: 84 (28x3) tablets.
Al/PVC/PVDC blister of 10 tablets. Such 10 blisters per box. Pack size: 100 (10x10) tablets.
Al/PVC/PVDC blister of 28 tablets. Such 3 or 24 blisters per box. Pack sizes: 84 (28x3), 672 (28x24).
Al/PVC/PE/PVDC blister of 28 tablets. Such 3, 10 or 24 blisters per box. Pack sizes: 84 (28x3), 280 (28x10), 672 (28x24).

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For any information about this medicinal product, please contact the supplier.

This leaflet was last approved in July 2011. Section 6 updated in September 2016.

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