

RHZ Kid Dispersible Tablet (DT)

Rifampicin 75 mg, Isoniazid 50 mg and Pyrazinamide 150 mg Dispersible Tablets

What is in this leaflet

1. What RHZ Kid DT is used for
2. How RHZ Kid DT works
3. Before you use RHZ Kid DT
4. How to use RHZ Kid DT
5. While you are using it
6. Side effects
7. Storage and Disposal of RHZ Kid DT
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What RHZ Kid DT is used for

RHZ Kid DT is a combination of three medicines that act against the bacteria that cause tuberculosis (TB). The active substances in RHZ Kid DT are:

- Isoniazid
- Rifampicin
- Pyrazinamide

RHZ Kid DT is used for the initial treatment of tuberculosis in children weighing less than 25 kg.

RHZ Kid DT may be given alone or together with another TB medicine.

This product is intended for use in children. Nonetheless, safety information is provided for adult health issues such as liver disease, pregnancy and breast-feeding, to allow full access to all relevant information.

How RHZ Kid DT works

RHZ Kid DT contains three different medicines called isoniazid, rifampicin and pyrazinamide. They all belong to a group of medicines called anti-tuberculous drugs. They work by killing the bacteria that cause tuberculosis.

Before you use RHZ Kid DT

- When you must not use it

Do not take RHZ Kid DT if you:

- are hypersensitive (allergic) to isoniazid, pyrazinamide, to rifampicin or related medicines called rifamycins or to any of the other ingredients of RHZ Kid DT (see section "What RHZ Kid DT contains").

- are experiencing new (acute) liver problems
- have previously had liver problems (hepatitis) caused by RHZ Kid DT, rifampicin or isoniazid
- have gouty arthritis or hyperuricemia (high levels of uric acid in the blood)
- have severe kidney problems
- have a condition called porphyria
- Are taking certain medicines:
 - **Voriconazole** (a medicine used to treat fungal infections)
 - **HIV infection medicines:** atazanavir, bicitgravir/ emtricitabine/ tenofovir alafenamide, darunavir, doravirine, elvitegravir/ cobicistat, etravirine, fosamprenavir, lopinavir, nevirapine, rilpivirine, ritonavir, tipranavir
 - **Chronic hepatitis C medicines:** daclatasvir, elbasvir/ grazoprevir, glecaprevir/ pibrentasvir, ledipasvir/ sofosbuvir, ombitasvir/ paritaprevir/ ritonavir, sofosbuvir
 - **Malaria medicines:** artemisinin and its derivatives (artemether, artemotil, artesunate, dihydroartemisinin)

Do not take RHZ Kid DT if any of the above apply to you.

If you are not sure about anything, ask your health care provider.

- Before you start to use it Warnings and precautions

The rifampicin in RHZ Kid DT may cause severe allergic reactions such rash, anaemia, low platelet count, difficulty breathing, shock, fever or kidney failure as thrombocytopenia, purpura, haemolytic anaemia, dyspnoea and asthma-like attacks, shock or renal failure. You should stop taking RHZ Kid DT immediately if you experience a severe allergic reaction. If you experience such a reaction, you must never again be treated with rifampicin.

Talk to your health care provider before taking RHZ Kid DT.

Tell your doctor if you have one of the following illnesses before taking this medicine:

- Kidney problems
- Liver problems
- Diabetes
- Epilepsy
- Inflammation of peripheral nerves or the optic nerve
- Problems with vision
- Chronic alcoholism
- Malnutrition (underfeeding)
- Psychosis (mental disorder)

Talk to your health care provider if you have any of these conditions, as RHZ Kid DT may not be suitable for you, or your health care provider may need to carry out additional checks.

Your health care provider will check your blood for liver function and metabolic changes before starting therapy, and at regular intervals during treatment with RHZ Kid DT.

Your health care provider will also check your vision before and during treatment. Contact your health care provider at once if you notice any problems with your eyesight in between checks.

RHZ Kid DT may cause liver disease (hepatitis). You should look out for symptoms that might be due to liver damage, such as unexplained loss of appetite, nausea, vomiting, dark urine, yellow coloration of the skin and of the whites of the eyes (jaundice), persistent tiredness for more than 3 days and abdominal (belly) pain and tenderness. If these occur, you should immediately talk to your health care provider.

You may be at special risk for developing hepatitis if:

- you are older than 35 years
- you drink alcoholic beverages daily (see "RHZ Kid DT with food and drink")
- you have a chronic liver disorder
- you are a user of injection drugs (e.g., heroin)

RHZ Kid Dispersible Tablet (DT)

Rifampicin 75 mg, Isoniazid 50 mg, Pyrazinamide 150 mg Dispersible Tablets

If any of these apply to you, your health care provider will check your liver function more often.

Furthermore, you will be carefully monitored if:

- you use other long-term medication at the same time (see “Other medicines and RHZ Kid DT”),
- you suffer from tingling in the hands and feet (peripheral neuropathy),
- you are pregnant
- you have HIV infection.

If you get flu-like symptoms such as fever, headache, muscle aches etc, you should report this to your health care provider straight away, since RHZ Kid DT may be the cause.

Tingling in the hands and feet (peripheral neuropathy) is the most common side effect of isoniazid, one of the active substances in RHZ Kid DT (see “Possible side effects”). You should report any such symptoms to your health care provider. Your health care provider may prescribe vitamin B6 (pyridoxine) to take during treatment with RHZ Kid DT, since it reduces the risk of developing neuropathy.

If you are hypersensitive (allergic) to ethionamide or niacin (nicotinic acid), you should tell your health care provider, because you may also be hypersensitive to RHZ Kid DT.

If you are taking cortisone or any cortisone-like medicines (called corticosteroids), you should say this to your health care provider, since the cortisone dose may have to be increased while you are taking RHZ Kid DT.

RHZ Kid DT causes a reddish orange discoloration of body fluids such as urine, sputum and tears as well as of your stool. This is due to rifampicin, and does not require medical attention. Also, contact lenses can become stained due to RHZ Kid DT.

RHZ Kid DT may reduce the effectiveness 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 RHZ Kid DT.

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

You should take RHZ Kid DT regularly every day. Do not interrupt or stop your treatment without discussing it with your health care provider.

Pregnancy and breast-feeding

If you become pregnant, think you may be, or are planning to become pregnant, talk to your health care provider to discuss the potential benefits and risks of the tuberculosis therapy for you and your baby.

Isoniazid and rifampicin pass in small amounts into the breast milk. No ill effects have been reported in breast-fed infants whose mothers were receiving these medicines. However, there is not enough medicine in breast milk to treat or protect your child from tuberculosis.

Other ingredient of RHZ Kid DT

RHZ Kid DT contains 3.13 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

- Taking other medicines

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The active substances in RHZ Kid DT can affect the action of a great number of other medicines. Other medicines may also affect the action of RHZ Kid DT. Side effects of either medicine may become worse, or the medicines may become less effective. Your health care provider may need to recommend a different medicine or may adjust your dose or carry out additional checks.

You must **not** take RHZ Kid DT with:

- **voriconazole** (a medicine used to treat fungal infections).
- **HIV infection medicines:** atazanavir, bictegravir/emtricitabine/tenofovir alafenamide, darunavir, doravirine, elvitegravir/cobicistat, etravirine, fosamprenavir, lopinavir, nevirapine, rilpivirine, ritonavir, tipranavir
- **Chronic hepatitis C medicines:** daclatasvir, elbasvir/grazoprevir, glecaprevir/pibrentasvir, ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir, sofosbuvir
- **Malaria medicines:** artemisinin and its derivatives (artemether, artemotil, artesunate, dihydroartemisinin)

As well as the medicines above, the active agents in RHZ Kid DT may also interact with a great number of other medicines. As a result, your health care provider may change the dose of your medicine and/or monitor you more closely for side effects. Medicines that may interact with RHZ Kid DT include:

- many medicines for **HIV infection** (e.g., zidovudine, efavirenz, raltegravir, maraviroc)
- medicines to treat **fungal infections** (e.g., ketoconazole, fluconazole, itraconazole)
- **antibiotics** (e.g., chloramphenicol, clarithromycin, dapsone, doxycycline, ethionamide, para-aminosalicylic acid, trimethoprim)
- medicines to treat **malaria** (e.g., atovaquone, chloroquine, mefloquine, quinine, lumefantrine)
- medicines to relieve **pain** (e.g., morphine, paracetamol, etoricoxib)
- medicines to treat **epileptic seizures** (e.g., phenytoin, carbamazepine, valproate, lamotrigine, phenobarbital)
- **immunosuppressant medicines**, often used to prevent rejection (e.g., ciclosporin, tacrolimus)
- medicines to treat **heart conditions** (e.g., verapamil, digoxin)
- medicines used to manage **blood pressure**, including medicines called beta blockers (e.g., atenolol) and calcium-channel blockers (e.g., amlodipine)

RHZ Kid Dispersible Tablet (DT)

Rifampicin 75 mg, Isoniazid 50 mg, Pyrazinamide 150 mg Dispersible Tablets

- medicines for **prevention of blood clots** (e.g., warfarin)
- medicines to **lower blood cholesterol** (e.g., simvastatin, atorvastatin)
- medicines to **control stomach acid or ulcers** (e.g., antacids containing aluminium hydroxide, ranitidine. If taking aluminium hydroxide cannot be avoided, take RHZ Kid DT 1 hour before this antacid.
- medicines used to **relieve anxiety or help you sleep** (e.g., benzodiazepines such as diazepam, flurazepam, triazolam, midazolam; zolpidem, zopiclone)
- medicines for the treatment of **certain psychiatric conditions** (neuroleptics, e.g., chlorpromazine, haloperidol, clozapine, and antidepressants, e.g., amitriptyline)
- corticosteroids (e.g., prednisolone, medicines for the treatment of inflammations and other diseases, such as asthma or rheumatoid arthritis)
- some medicines to treat **diabetes** (e.g., glibenclamide, gliclazide, repaglinide)
- **oral contraceptive pills**. An additional method of contraception is recommended.
- medicines used in surgery (e.g., alfentanil, enflurane)
- codeine (medicine to treat cough)
- methadone (medicine used to manage drug addiction)
- disulfiram (medicine used for the treatment of chronic alcoholism)
- praziquantel (medicine used to treat certain parasite infections)
- typhoid vaccine taken by mouth

Taking any of these medicines together with RHZ Kid DT may be unsuitable or require dose adjustment, so it is very important that you tell your health care provider about any other medicines that you may take.

Alcohol should be avoided while taking RHZ Kid DT because it increases the risk of liver damage.

Eating cheese or fish (histamine- or tyramine-rich food) while being treated with RHZ Kid DT may cause itchiness and redness of the skin, sensation of feeling hot, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, and lightheadedness. Cheese

and fish should be avoided if these effects occur while taking RHZ Kid DT

How to use RHZ Kid DT

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

RHZ Kid DT should always be taken exactly as described by the health care provider. You should check with your child's health care provider if you are not sure.

RHZ Kid DT is usually given for the first two months of tuberculosis treatment. Your child's health care provider will decide on the duration of treatment for your child. The usual doses are shown in the table below:

Patients' weight	Dose
4 to less than 8 kg	1 tablet once daily
8 to less than 12 kg	2 tablet once daily
12 to less than 16 kg	3 tablets once daily
16 to less than 25 kg	4 tablets once daily
25 kg or more	Adult dosages recommended

RHZ Kid DT is not recommended for adults or children who weigh 25 kg or more.

If your child has a kidney disease, your child's doctor may prescribe rifampicin, isoniazid and pyrazinamide separately rather than in a single tablet.

RHZ Kid DT should be taken on an empty stomach (at least one hour before or two hours after a meal).

Disperse the tablets in drinking water before taking the dose. Each tablet should be dispersed in 10 mL water.

Instructions for giving RHZ Kid DT tablets

Look up the patient's weight in the table above.

1. Then look for the number of tablets that will be required.
2. Place the required volume of water in a small, clean cup or bowl and add the required number of tablets.
3. Stir gently until the tablets disperse.
4. Give the child the entire medicine mixture immediately using a syringe.
5. Rinse the cup with a little additional water and give the child to drink to ensure the entire dose is taken.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Your child should keep taking the medicine for as long as the health care provider has ordered, even if feeling better. If the medicine is stopped too soon, the infection may not be completely cured. Treatment should not be stopped unless the health care provider says so.

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

- If you forget to use it

If a dose is missed, a dose should be taken as soon as possible, unless the next scheduled dose is due within 6 hours. Skip the missed dose if it is almost time for the next regular dose. A dose should not be doubled to make up for a missed dose.

- If you use too much (overdose)

Taking too many RHZ Kid DT may cause vomiting, gastrointestinal disturbances, fever, headache, dizziness, slurring of speech, hallucinations and visual disturbances. The skin may become discolored reddish-orange and there may be facial swelling and itching. You should immediately contact a health care provider or the nearest hospital emergency department for further advice.

While you are using RHZ Kid DT

- Things you must do

Use your medicine exactly as your doctor has told you.

RHZ Kid Dispersible Tablet (DT)

Rifampicin 75 mg, Isoniazid 50 mg, Pyrazinamide 150 mg Dispersible Tablets

Tell all the doctors, dentists and pharmacists treating you that you are using RHZ Kid DT

Tell your doctor immediately if you become pregnant while using this medication.

- **Things you must not do**

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give RHZ Kid DT to anyone else, even if they have the same symptoms or condition as you.

- **Things to be careful of**

Driving and using machines

RHZ Kid DT can cause dizziness, drowsiness or affect your eyesight. If you experience any of these side effects while taking RHZ Kid DT, do not drive and do not use any hazardous tools or machines.

Side effects

Like all medicines, RHZ Kid DT can cause side effects, although not everybody gets them. It is important that you tell your health care provider of any change in your health during treatment. If you get any of the following symptoms of a severe allergic reaction, tell your health care provider **immediately** or go to the emergency department at your nearest hospital:

- Sudden difficulty in breathing, speaking and swallowing
- Swelling of lips, tongue, face or neck
- Extreme dizziness or collapse

If you get any of the following side effects **contact your health care provider as soon as possible**:

- Inflammation of the pancreas, which causes severe pain in the abdomen (belly) and back
- Severe extensive skin damage with blistering or peeling of the skin
- Yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, tiredness, weakness, feeling generally unwell, loss of appetite, pain just below your ribs, nausea or

vomiting caused by liver problems (hepatitis)

- Diarrhoea that is serious, lasts a long time or has blood in it with belly pain or fever: This can be a sign of serious bowel infection (pseudomembranous colitis)
- Unexplained bleeding, small purple spots or blood blisters in the skin (thrombocytopenic purpura)
- Vision disturbances like blurred vision, eye pain, red-green colour blindness or even loss of vision
- Shortage of white blood cells, accompanied by sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis).

These are all serious side effects. You may need urgent medical attention.

The following side effects may affect people taking RHZ Kid DT:

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 health care provider may prescribe a vitamin B6 (pyridoxine) supplement, in order to counteract this.
- increased liver enzymes as measured in blood samples. 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 health care provider may decide to stop treatment with RHZ Kid DT
- flushing
- fever, chills
- increased levels of uric acid in the blood (hyperuricaemia)
- joint pain

Common side effects (may affect up to 1 in 10 people):

- reddish discoloration of body fluids such as urine, sputum, tears, saliva and sweat
- staining of contact lenses
- belly pain, feeling bloated
- loss of appetite
- feeling sick (nausea)
- vomiting
- skin reactions with rash and/or itching

- tiredness, drowsiness
- headache
- lightheadedness or dizziness
- reddening of the eyes.

Uncommon side effects (may affect up to 1 in 100 people):

- inflammation of the liver (hepatitis), jaundice (yellowing of skin or eyes)
- epileptic seizures
- inflammation of the brain
- personality changes and difficulty remembering
- damage to the optic nerve resulting in effects on vision, eye pain.

Rare side effects (may affect up to 1 in 1000 people):

- inflammation of the stomach lining (gastritis)
- inflammation of the pancreas
- infection of the intestines (bowel infection, pseudomembranous colitis)
- diarrhoea
- liver failure
- inflammation of the kidney (nephritis)
- skin sensitivity to light (photosensitivity reactions)
- severe skin reactions with rashes, fever and skin breakdown or blistering (Steven-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, pemphigoid)
- muscle weakness, muscle pain and loss of coordination
- confusion, altered sense of reality
- triggering of porphyria (a metabolic condition)
- menstrual disturbances
- low white blood cell counts
- low blood platelet counts (thrombocytopenia), purple patches on the skin like bruising (purpura)
- inflammation or swelling of the conjunctiva or pink eye (conjunctivitis)

Very rare side effects (may affect up to 1 in 10 000 people):

- anaphylaxis (severe allergic reaction)
- a vitamin deficiency syndrome called pellagra (with e.g. dementia, loose stools and skin inflammation)
- inflammation of the lungs (pneumonitis)

RHZ Kid Dispersible Tablet (DT)

Rifampicin 75 mg, Isoniazid 50 mg, Pyrazinamide 150 mg Dispersible Tablets

Side effects of which it is not known how often they may occur

- gout
- allergic reactions with fever, muscle aches, and cough
- reduced function of adrenal glands
- breakdown of red blood cells (haemolysis)
- small blood clots throughout the body (disseminated intravascular coagulation)
- bone pain
- collapse, shock (steep fall in blood pressure)
- fluid build-up under the skin (oedema)
- high blood pressure
- inflammation of blood vessels (vasculitis)
- flushing
- build-up of acid in the body (metabolic acidosis), increased blood levels of glucose
- dry mouth, flatulence (gas), constipation
- painful urination
- acne
- systemic lupus erythematosus, antibodies against the body's own tissues, arthritis, rheumatic disorders
- deafness, tinnitus
- vertigo
- raised mood
- sleep disorders
- breast enlargement in men (gynaecomastia)
- decreased red blood cell counts (anaemia), possibly leading to fatigue, weakness and shortness of breath
- bleeding
- weight loss

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of RHZ Kid DT

- Storage
Keep out of the reach and sight of children.
Store below 30°C. Store in a dry place. Protect from light.
- Disposal
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.

Product Description

- What it looks like
Brick red mottled, circular, uncoated biconvex tablets having deep score on one side and plain surface on other side.

The score line is not intended for breaking the tablet.

- Ingredients

- Active ingredient(s)
 - Isoniazid
 - Pyrazinamide
 - Rifampicin.
- Inactive ingredients
 - Microcrystalline cellulose
 - Crospovidone
 - Povidone
 - Bleached Shellac
 - Croscarmellose Sodium
 - Aspartame
 - Strawberry Dry Mix
 - Magnesium stearate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

- MAL number(s):
MAL25056006ACZ

Manufacturer:

OXALIS LABS

Village Theda, P.O. Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh, India

Product Registration Holder:

Macleods Pharmaceuticals Sdn. Bhd.
A2-27-1 Soho Suites KLCC, Jalan Perak, 50450 Kuala Lumpur, Malaysia

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