

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets *

Read all of this leaflet carefully before you start giving this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets are and what it is used for
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3. How to take Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets
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1. WHAT ISONIAZID/PYRIDOXINE HYDROCHLORIDE/SULFAMETHOXAZOLE/TRIMETHOPRIM 300 mg/25 mg/800 mg/160 mg TABLETS IS AND WHAT IT IS USED FOR

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets contains isoniazid, pyridoxine hydrochloride, sulfamethoxazole and trimethoprim.

Isoniazid is an antibiotic that works against *Mycobacteria tuberculosis*, the bacterium that causes tuberculosis. Pyridoxine is a vitamin that prevents some side effects of isoniazid. Sulfamethoxazole and trimethoprim are also antibiotics that work against different types of organisms including those that can cause serious infections in patients who have human immunodeficiency virus (HIV) infection.

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets is used in adolescents and children weighing over 14 kg who have HIV infection to prevent malaria, tuberculosis and some other infection.

The health care provider will use the official guidelines to check that the medicine is suitable for you.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. WHAT YOU NEED TO KNOW BEFORE YOUR TAKE ISONIAZID/PYRIDOXINE HYDROCHLORIDE/SULFAMETHOXAZOLE/TRIMETHOPRIM 300 mg/25 mg/800 mg/160 mg TABLETS

You must not take Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets if you:

- are allergic (hypersensitive) to isoniazid, pyridoxine, sulfamethoxazole (or another sulfonamide) and trimethoprim or to any of the other ingredients of Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets (see section 6 What Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets contains)
- has ever had serious liver problems and any liver problems caused by isoniazid
- have had severe side effects from isoniazid such as drug fever, chills and arthritis
- have had serious skin side effects (such as Stevens-Johnson syndrome or toxic epidermal necrolysis) with sulfamethoxazole/trimethoprim
- have porphyria, a rare blood problem which can affect your skin or nervous system
- blood problems caused by sulfamethoxazole or trimethoprim, including some types of anaemia (which can make you look pale and feel tired and breathless) and thrombocytopenia (which can make you bruise and bleed easily)
- if you are taking medicines that can cause blood problems such as clozapine and amodiaquine or severe skin problems such as sulfadoxine/pyrimethamine

If you are not sure if you should take Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets, talk to your health care provider before taking the medicine.

Take special care with Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets

Check with your health care provider before taking Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets if you:

- are suffering from a recent illness. If you have malaria, tuberculosis and other infections then you may need treatment with a different medicine
- are allergic to medicines like ethionamide, pyrazinamide, nicotinic acid (niacin)
- have severe allergies or asthma
- have low level of folic acid, which can make you look pale and feel tired or breathless
- have kidney disease
- have liver disease or you have a risk of liver problems (age over 35 years, if you drink alcohol every day or if you inject drugs)
- have a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency
- have diabetes
- have had blood tests which show high level of potassium in your blood

If any of the above apply to you or if you are not sure, talk to your health care provider before you take Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets.

Talk to your health care provider as soon as possible if you get:

- signs of liver damage such as lack of appetite, nausea, vomiting, dark urine, yellowing of the skin and the eyes, tiredness, weakness and abdominal pain (especially in the right upper area of the belly)

- signs of pancreatitis such as pain in the upper belly, bellyache that spreads to the back, bellyache that gets worse after eating, fever, rapid pulse, nausea and vomiting
- tingling in the hands and feet
- rash with blistering, changes in skin colour, damage to the inside of the mouth, sore throat, fever, joint pain, and paleness because this may be signs of serious reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis
- signs of anaemia (such as look pale and feel tired and breathless), thrombocytopenia (such as bruising and bleeding readily) and reduced white cell count (which can cause sore throat and infections)

Taking other medicines

Tell your health care provider if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your health care provider if you are taking any of the following medicines:

- diuretics (medicines that increase urine output)
- anticoagulants (medicines like warfarin which prevents blood clots)
- epilepsy medicines including carbamazepine, ethosuximide, phenytoin, primidone and valproate
- medicines for anxiety and insomnia such as diazepam and midazolam
- medicines used during operations including general anaesthetics (medicines used to put you to sleep during an operation, such as enflurane) and alfentanil (a strong painkiller)
- medicines used for heart and circulation problems such as digoxin, propranolol, ACE inhibitors (such as enalapril and quinapril) and angiotensin receptor blockers (such as irbesartan, valsartan and losartan)
- medicines for malaria such as amodiaquine, sulfadoxine/pyrimethamine
- medicines for fungal infections such as itraconazole and ketoconazole
- paracetamol (also called acetaminophen, a painkiller)
- medicines for some mental disorders such as chlorpromazine, clozapine and haloperidol)
- methotrexate (used for conditions such as arthritis and also for cancer)
- ciclosporin (used for preventing transplant rejection reactions)
- prednisolone used to reduce inflammation
- theophylline (used for breathing problems)
- medicines for diabetes
- antacids (medicines used for stomach upset)

Taking care with food and drinks

- if you drink alcohol every day or drink excessively while taking Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets, you have a high chance of developing liver problems
- eating foods like cheese and fish while taking Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets can cause unpleasant effects such as skin redness or itching, feeling hot, rapid or pounding heartbeat, sweating, chills, headache and lightheadedness

Pregnancy and breastfeeding

Speak with your health care provider if you are pregnant, planning to have a baby or if you are breastfeeding.

Driving and using machines

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets does not usually affect your ability to drive or to use machines but you must not drive or use machinery if your condition or any side effects might affect your alertness or muscle movement.

3. HOW TO TAKE ISONIAZID/PYRIDOXINE HYDROCHLORIDE/ SULFAMETHOXAZOLE/TRIMETHOPRIM 300 mg/25 mg/800 mg/160 mg TABLETS

Your health care provider will tell you when to start treatment with Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets and how long you need to take it for.

You should take the tablet at around the same time every day. It is best to take it on at least one hour before a meal or at least two hours after a meal. To give half a tablet to a child, break the tablet using the score-lines. You must not crush or chew the tablets and you should swallow the tablets with water.

Adults

The recommended dose for adults is 1 tablet once a day.

Children and adolescents

The recommended doses for children and adolescents depend on body weight and are shown below.

Body weight	Dose
Under 14 kg	Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets is not suitable; use alternative products containing lower amounts of the active ingredients to give suitable doses of isoniazid, pyridoxine, sulfamethoxazole and trimethoprim
14–24.9 kg	½ tablet once a day
25 kg and over	1 tablet once a day

If you take more Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets than you should have

If you have taken too much Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets, tell your health care provider.

If you miss a dose of Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets

You should take the medicines at the right time to have the best chance of preventing infections.

If you miss a dose and it is less than 6 hours when you should have taken it then take the missed dose as soon as you can and take the next dose at the usual time. If more than 6 hours have passed since the dose was due, you should skip the missed dose and take the next one at the usual time. You must not take a double dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets can cause side effects but not everybody gets them.

Common and very common side effects (occurring in up to 1 person in 10) are:

- nerve problems like tingling, nausea, diarrhoea
- headache
- yeast infections (such as thrush)

- rash
- blood tests showing high level of potassium and raised liver enzymes

Uncommon side effects (occurring in 1 to 10 people in 1000)

- vomiting
- liver injury
- fits and brain function disorders
- memory disorders and mental disorders

Very rare side effects (occurring in fewer than 1 in 10 000 people)

- swollen tongue, mouth and lips
- severe diarrhoea because of an infection (Clostridium difficile infection)
- decreased appetite
- jaundice and liver damage
- blood tests showing low blood sugar, low sodium levels, metabolic acidosis, low levels of red and white blood cells and of platelets, methaemoglobinaemia
- break-down of red blood cells (in patients with glucose-6-phosphate dehydrogenase deficiency)
- swelling of the lining of the brain causing headache and fever
- serious rashes (including Stevens-Johnson syndrome, toxic epidermal necrolysis)
- swollen blood vessels
- systemic lupus erythematosus (with joint pain, stiffness, swelling, rash, tiredness, weight loss and chest pain)
- cough, breathing difficulty, lung damage
- kidney damage
- joint and muscle pain
- inflammation in the eye causing pain and redness
- rash or sunburn caused by sunlight or bright light

Other side effects (frequency not known)

- flatulence (gas), weight loss, dry mouth, abdominal pain, pancreatitis, constipation
- raised blood sugar, pellagra (causing diarrhoea, skin rash and mental disorders)
- disturbances in heart rhythm which can lead to serious complications
- tremor and overactive muscle reflexes
- confusion, disorientation, hallucinations, withdrawal, nervousness and sleeplessness
- severe allergic reactions, idiopathic thrombocytopenic purpura (causing excessive bruising and bleeding)
- urinary retention, inability to produce urine, formation of crystals in the urine
- arthritis, muscle wasting
- loss of vision and nerve swelling
- drug reaction with eosinophilia and systemic symptoms (a type of severe drug reaction), itching

**5. HOW TO STORE ISONIAZID/PYRIDOXINE HYDROCHLORIDE/
SULFAMETHOXAZOLE/TRIMETHOPRIM 300 mg/25 mg/800 mg/160 mg TABLETS**

Keep out of the reach and sight of children.

Do not store above 30° C

Do not use Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets after the expiry date printed on the pack.

Medicines should not be disposed of in waste water or household waste. Ask your pharmacist or health care provider 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 Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets contains

The active substance in Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets are isoniazid, pyridoxine hydrochloride, sulfamethoxazole and trimethoprim. The other ingredients are as follows:

Maize starch
Sodium starch glycolate
Povidone
Docusate sodium benzoate
Magnesium stearate
sodium benzoate

What Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets looks like and contents of the pack

White to off-white coloured capsule shaped, biconvex uncoated tablets scored on both the sides. The tablet can be divided into two equal doses.

The tablets are packaged in white 65 cc HDPE bottle with white 45 mm HDPE cap with induction sealing and rayon sanicoil, containing 30 tablets.

Supplier and Manufacturer

Supplier

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