

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA762 trade name][†]

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly .*

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

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HA762 trade name] is and what it is used for
2. What you need to know before you take [HA762 trade name]
3. How to take [HA762 trade name]
4. Possible side effects
5. How to store [HA762 trade name]
6. Contents of the pack and other information

1. What [HA762 trade name] is and what it is used for

[HA762 trade name] is for people living with HIV who weigh over 14 kg. It can stop you catching several infections including tuberculosis (TB), *Pneumocystis jiroveci* pneumonitis (a lung infection), malaria, and toxoplasmosis (a parasite infection that you can catch from undercooked food and dirty water).

People with HIV infection catch infections more easily if their immune system (the body's defences) has been weakened.

The active substances in [HA762 trade name] are isoniazid, pyridoxine hydrochloride, sulfamethoxazole and trimethoprim. Isoniazid, sulfamethoxazole and trimethoprim are antibiotics, and pyridoxine hydrochloride is a vitamin that can stop certain side effects caused by isoniazid.

2. What you need to know before you take [HA762 trade name]

You must not take [HA762 trade name] if you:

- are allergic (hypersensitive) to isoniazid 300 mg, pyridoxine, sulfamethoxazole (or another sulfonamide) and trimethoprim or to any of the other ingredients of [HA762 trade name] (see section 6 "What [HA762 trade name] contains")
- have ever had serious liver problems or any liver problems caused by isoniazid
- have had severe side effects from isoniazid such as drug fever, chills and arthritis
- have severe kidney problems but you are not receiving medical care or follow up for them
- have porphyria, a rare blood problem which can affect your skin or nervous system

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- have 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)

You must also not take [HA762 trade name] if you take any of the following medicines:

- amodiaquine (for malaria)
- clozapine (for certain mental disorders)
- sulfadoxine/pyrimethamine, alone or in combination with artesunate (for malaria)

If you are not sure if you should take [HA762 trade name], talk to your health care provider before taking the medicine.

Take special care with [HA762 trade name]

Check with your health care provider before taking [HA762 trade name] 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
- have severe allergies or asthma
- are allergic to medicines like ethionamide, pyrazinamide, nicotinic acid (niacin)
- have 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
- have liver disease or you are at higher risk of liver problems (for example, if you are over 35 years of age, if you drink alcohol every day, if you are not eating well enough or if you inject drugs)
- have blood problems or low level of folic acid, which can make you look pale and feel tired or breathless
- 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 or if you have kidney disease
- have any condition that causes fits (seizures) or if you have a mental disorder

If any of the above apply to you or if you are not sure, talk to your health care provider before you take [HA762 trade name].

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)
- 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)
- cough and shortness of breath
- diarrhoea

Your health care provider will test your blood regularly to check for any problems with your liver.

If you take [HA762 trade name] for a long time, you may need to have regular urine and blood tests and you may be given folinic acid. You may have urine and blood tests if your kidneys are not working well.

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:

- antiviral medicines such as ganciclovir and zidovudine that can cause blood problems

- 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, procainamide, 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 and 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)
- disulfiram (used in people with alcohol drinking problems)
- 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 [HA762 trade name], you are at higher risk of developing liver problems
- eating foods like cheese and fish while taking [HA762 trade name] can cause unpleasant effects such as skin redness or itching, feeling hot, rapid or pounding heartbeat, sweating, chills, headache and light-headedness

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

[HA762 trade name] 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 affect your alertness or muscle movement.

3. How to take [HA762 trade name]

Your health care provider will tell you when to start treatment with [HA762 trade name] 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 at least one hour before a meal and at least two hours after a meal. To give half a tablet to a child, break the tablet using the score-line.

Do not crush or chew the tablet and swallow the tablet with water.

Adults

The dose for adults is 1 tablet once a day.

Children and adolescents

The dose for children and adolescents depends on body weight as shown below

Weight	Dose
Under 14 kg	[HA762 trade name] is not suitable; your health care provider will say which medicines to use
14–25 kg	½ tablet once a day
Over 25 kg	1 tablet once a day

If you take more [HA762 trade name] than you should have

If you have taken too much [HA762 trade name], tell your health care provider.

If you miss a dose of [HA762 trade name]

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 after 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, [HA762 trade name] can cause side effects but not everybody gets them.

Very common side effects (occurring in more than 1 person in 10)

- nerve problems (like pain, numbness, burning and tingling) but pyridoxine in [HA762 trade name] should prevent this
- blood tests showing high potassium level and temporarily raised liver enzymes (suggesting stress on the liver)

Common side effects (occurring in up to 1 person in 10)

- nausea (feeling sick), diarrhoea
- headache
- thrush (a fungal infection)
- rash

Uncommon side effects (occurring in up to 1 to 100)

- vomiting
- liver injury
- fits (seizures), brain disorder
- memory problems and mental disorders

Rare side effect (occurring in up to 1 in 1000 people)

- toxic epidermal necrolysis (a serious reaction with blistering in the skin, mouth eyes and genitals and flu-like effects)

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

- swollen tongue, mouth and lips
- severe diarrhoea (antibacterial-associated colitis)
- decreased appetite
- inflammation of the pancreas with severe pain in the belly and back
- jaundice and liver damage, blood tests showing raised bilirubin levels
- blood tests showing low blood sugar, low sodium levels, metabolic acidosis, low levels of red and white blood cells and of platelets, methaemoglobinaemia (resulting in reduced oxygen carried by the blood)
- 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
- nerve swelling and loss of muscle co-ordination
- feeling dizzy, spinning sensation, ringing or buzzing in the ear
- depression, hallucination
- severe allergic reactions including swelling of blood vessels, fever and swelling under the skin
- 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
- serious rashes (including Stevens-Johnson syndrome, toxic epidermal necrolysis)

Other side effects (frequency not known)

- flatulence (gas), weight loss, dry mouth, abdominal (belly) pain, 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, lack of energy or interest, nervousness and sleeping problems
- 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
- weakness, tiredness

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help improve understanding about the safety of this medicine.

5. How to store [HA762 trade name]

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

Do not store above 30°C. Store in the original container.

Do not use this medicine after the expiry date stated on the carton, blister or bottle, after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [HA762 trade name] contains

- The active ingredients are isoniazid 300 mg, pyridoxine hydrochloride 25 mg, sulfamethoxazole 800 mg and trimethoprim 160 mg.

- The other ingredients of [HA762 trade name] are:
 - Core tablet:* microcrystalline cellulose, hydroxypropyl cellulose, sodium starch glycolate, colloidal silicon dioxide, stearic acid, partially pregelatinized maize starch, docusate sodium, low-substituted hydroxypropyl cellulose and magnesium stearate
 - Film coat:* hypromellose, titanium dioxide, macrogol/PEG, talc, iron oxide yellow and iron oxide red

What [HA762 trade name] looks like and contents of the pack

Brown, film-coated, oval-shaped, biconvex, bevel edge, scored tablet, debossed with "S" and "T" on either side of score line on one side and "I" and "M" on either side of score line on the other side.

The tablet can be divided into two equal doses.

[HA762 trade name] are available in:

HDPE Bottle

White, round, HDPE bottle and closed with a white, opaque polypropylene screwcap with liner, without a desiccant. Pack size: 30 tablets.

Blister pack

Cold form Alu-OPA/PVC/Alu blister card. Each blister card contains 10 tablets. Pack size: 1 x 10 tablets.

Supplier

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad-500096
Telangana
India
E-mail: Imtiyaz.Basade@viatris.com

Manufacturer

Mylan Laboratories Limited
Plot No. 11,12 & 13
Special Economic Zone, Pharma Zone
Phase-II, Sector-III, Pithampur-454775
Dist. Dhar, Madhya Pradesh
India

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in September 2022.

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>