

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Pyrazinamide 400 mg Tablets* Pyrazinamide

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 any further questions, ask your doctor, health care provider or pharmacist.
- 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 are the same as yours.
- If you get 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 Pyrazinamide 400 mg Tablets is and what it is used for
2. What you need to know before you take Pyrazinamide 400 mg Tablets
3. How to take Pyrazinamide 400 mg Tablets
4. Possible side effects
5. How to store Pyrazinamide 400 mg Tablets
6. Contents of the pack and other information

1. WHAT PYRAZINAMIDE 400 MG TABLETS IS AND WHAT IT IS USED FOR

Pyrazinamide 400 mg Tablets is used in combination with other antituberculosis agents for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis*.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PYRAZINAMIDE 400 MG TABLETS

Do not take Pyrazinamide 400 mg Tablets

- if you are hypersensitive (allergic) to pyrazinamide or any of the other ingredients of Pyrazinamide 400 mg Tablets (see section 6, What Pyrazinamide 400 mg Tablets contains).
- if you have severe liver impairment
- if you have acute gout.

Warnings and precautions

If you have a kidney disease, diabetes, or a history of gout, your doctor will monitor you carefully.

In case of impaired kidney function your doctor may decide to adjust the dose.

Before starting therapy, and at regular intervals during treatment with Pyrazinamide 400 mg Tablets, your doctor or health care provider will check your blood for liver function and metabolic changes.

If you are hypersensitive to ethionamide, isoniazid or niacin (nicotinic acid), you should inform your doctor, because you may also be hypersensitive to Pyrazinamide 400 mg Tablets.

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

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

Other medicines and Pyrazinamide 400 mg Tablets

Please tell your doctor, health care 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 Pyrazinamide 400 mg Tablets, or Pyrazinamide 400 mg Tablets may affect their action.

Do not take Pyrazinamide 400 mg Tablets together with probenecid or allopurinol (medicines for treating gout).

Do not take Pyrazinamide 400 mg Tablets together with ofloxacin or levofloxacin, unless your doctor tells you so.

Pyrazinamide 400 mg Tablets with food and drink

Pyrazinamide 400 mg Tablets should preferably be taken without food.

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential benefits and risks of your tuberculosis therapy for you and your child.

Pyrazinamide is excreted into the breast milk of nursing mothers. However, no negative effects have been reported in breast-fed-infants, whose mothers were receiving pyrazinamide.

Driving and using machines

Pyrazinamide 400 mg Tablets can cause headache and dizziness and may impair your ability to drive and to use machines.

3. HOW TO TAKE PYRAZINAMIDE 400 MG TABLETS

Always take Pyrazinamide 400 mg Tablets exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The dose of Pyrazinamide 400 mg Tablets was decided by your doctor based on your body weight. Also, the dosing intervals (daily, thrice or twice weekly) most suitable for you was selected by your doctor or health care provider.

Take Pyrazinamide 400 mg Tablets always in combination with other antituberculosis medicines.

Daily regimen

25 mg/kg (20-30 mg/kg) body weight as a single daily dose.

Children weighing less than 30 kg should take 35 mg/kg (30-40 mg /kg) body weight as a single daily dose.

Number of Pyrazinamide 400 mg Tablets for daily treatment according to weight bands (children and adults)

Weight in kg	11-20	21-39	40-54	55-70	>70
Number of tablets per day	1	2	3	4	5

Intermittent regimen

35 mg/kg (30-40 mg/kg) body weight 3 times a week as a single dose or 50 mg/kg (40-60 mg/kg) body weight 2 times a week as a single dose.

If you have kidney disease your doctor may prescribe a reduced dose of Pyrazinamide 400 mg Tablets for you.

In patients requiring less than 400 mg pyrazinamide per dose, another formulation containing less pyrazinamide should be used.

Swallow Pyrazinamide 400 mg Tablets whole with water or another drink. Tablets should neither be crushed nor chewed. Pyrazinamide 400 mg Tablets should preferably be taken without food.

Pyrazinamide 400 mg Tablets will always be taken in combination with other antituberculosis medication; please make sure to follow the instructions within the supplied package leaflet(s).

If you take more Pyrazinamide 400 mg Tablets than you should

If you have taken too many tablets or if someone accidentally swallows some, you may develop liver damage and increases in blood levels of uric acid. Immediately contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Pyrazinamide 400 mg Tablets

When you have to take Pyrazinamide 400 mg Tablets daily: If you miss or forget to take a dose, take the missed dose as soon as possible, unless the next regular dose is scheduled within 6 hours.

When you have to take Pyrazinamide 400 mg Tablets two or three times per week: In case you miss or forget to take a dose, take the missed dose as soon as possible, unless the next regular dose is scheduled within 10 hours.

Skip the missed dose if it is almost time for your next regular dose.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Pyrazinamide 400 mg Tablets

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, your infection may not be completely cured.

You should not stop treatment unless your doctor or health care provider tells you to.

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, Pyrazinamide 400 mg 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 Pyrazinamide 400 mg Tablets or those caused by any other medicines you may be taking at the same time.

For this reason, it is important that you inform your doctor or health care provider of any change in your health.

The most important adverse effect of pyrazinamide is liver damage, ranging from increases in blood transaminases (markers of liver injury) without clinical symptoms to liver function impairment with clinical symptoms, e.g. itching and yellowing of the skin, and in rare cases also to fatal liver failure. Side effects observed during treatment with pyrazinamide are listed below. Frequencies are defined as very common (greater than 1 in every 10 patients treated), common (greater than 1 in every 100 patients treated), uncommon (between 1 in 1,000 and 1 in 100 patients treated), rare (between 1 in 10 000 and 1 in 1000 patients treated), very rare (under 1 in 10 000 patients treated). Sometimes, no frequency data can be given (category: 'not known').

Nervous system disorders:

Not known: headache, dizziness, nervousness, difficulty sleeping.

Gastrointestinal disorders:

Common: nausea, vomiting

Not known: abdominal cramps, loss of appetite.

Hepatobiliary disorders:

Very common: Increased liver enzymes

Uncommon: jaundice (yellowing of the skin and eye white)

Rare: liver failure.

Metabolism and nutrition disorders

Very common: high levels of uric acid in the blood (hyperuricaemia)

Very rare: pellagra (disease presenting with diarrhoea, skin inflammation and impaired brain function [dementia], caused by a lack of niacin, a certain vitamin), aggravated porphyria (disorder of certain enzymes in the synthesis pathway of the red blood pigment).

Renal and urinary disorders

Not known: inflammation of the kidney (interstitial nephritis).

Skin and subcutaneous tissue disorders:

Rare: rash, sensitivity to (sun-)light, urticaria.

General disorders

Very common: flushing

Not known: general aches and pains, fever, weight loss, allergic reactions.

Blood and lymphatic systems disorders:

Not known: anaemia (low red blood cell count), and neutropenia (low white blood cell count). If the number of red blood cells is reduced you may have symptoms of tiredness or breathlessness and a reduction in your white blood cell count can make you more prone to infections.

Decrease of platelets (blood cells important for blood clotting). If you have a low platelet count you may notice that you bruise more easily.

Musculoskeletal disorders:

Very common: joint pain (without signs of joint inflammation)

Not known: gouty arthritis.

Vascular disorders:

Not known: hypertension (high blood pressure).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist as soon as possible.

5. HOW TO STORE PYRAZINAMIDE 400 MG TABLETS

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

Do not store above 30°C, protect from moisture.

Do not use Pyrazinamide 400 mg Tablets after the expiry date which is stated on the bottle after expiry date. The expiry date refers to the last day of that month.

Do not use Pyrazinamide 400mg Tablets if you notice swelling of tablets.

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 Pyrazinamide 400 mg Tablets contains

The active ingredient is 400 mg pyrazinamide.

The other ingredients are: Maize starch, Povidone, Sodium starch glycolate, Purified talc, Colloidal anhydrous silica, Magnesium stearate.

What Pyrazinamide 400 mg Tablets looks like and contents of the pack

White, circular, flat bevelled edged uncoated tablets plain on both sides.

The tablets should not be divided.

Low density polyethylene bag (500 tablets) further packed in HDPE container sealed with aluminium tagger.

Low density polyethylene bag (1000 tablets) further packed in HDPE container sealed with aluminium tagger.

Al/PVC blister of 10 or 28 tablets. Such 3, 10 or 24 blisters per box. Pack sizes: 30 (3x10), 84(28x3), 100 (10x10), 240(24x10), 280(28x10), 672(28x24)

Al/PVDC Silver Coated PVC blister of 10 or 28 tablets. Such 3, 10 or 24 blisters per box. Pack sizes: 30(3x10), 84(28x3), 100(10x10), 240(24x10), 280 (28x10), 672 (28x24) tablets.

Supplier

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For any information about this medicinal product, please contact the local representative of the supplier:

CAMBODIA Curewel International Co ltd	No.34, Street 208, Sangkat Boeung	Raing Khan Daun Penh, Phnom Penh, Cambodia. Tel: 855 23
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WHOPAR Part 3

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