



PACKAGE LEAFLET: INFORMATION FOR THE USER

**PENTOXIFYLLINE
EXTENDED RELEASE TABLETS
400MG
TAJ PHARMA**

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What Pentoxifylline is and what it is used for
2. Before you take Pentoxifylline
3. How to take Pentoxifylline
4. Possible side effects
5. How to store Pentoxifylline
Further information

1. WHAT PENTOXIFYLLINE IS AND WHAT IT IS USED FOR

Pentoxifylline contains a medicine called pentoxifylline.

This belongs to a group of medicines called peripheral vasodilators. It works by increasing the blood flow to the arms and legs.

Pentoxifylline can be used to treat:

- Peripheral vascular disease (poor circulation to the arms and legs).
- Intermittent claudication (pain on walking or at rest caused by poor circulation to the legs).

2. BEFORE YOU TAKE PENTOXIFYLLINE

Do not take Pentoxifylline if:

- You are allergic (hypersensitive) to pentoxifylline, other similar medicines such as theophylline or aminophylline or to any of the other ingredients of Pentoxifylline (see Section 6: Further Information)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have heart problems or have recently had a heart attack
- You have severe palpitations (very fast and uneven heartbeats)
- You have had a stroke with bleeding in the brain (cerebral haemorrhage)
- You have had bleeding in the eye (retinal haemorrhage)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your

doctor or pharmacist before taking Pentoxifylline.

Take special care with Pentoxifylline

Check with your doctor or pharmacist before taking your medicine if:

- You feel dizzy, light-headed or faint when you stand or sit up too quickly (hypotension)
- You have problems with the blood supply to your heart caused by hardening or narrowing of the arteries
- You have liver or kidney problems

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Pentoxifylline.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Pentoxifylline can affect the way some other medicines work. Also some medicines can affect the way Pentoxifylline works.

In particular, tell your doctor if you are taking any of the following:

Pentoxifylline may increase the effect of the following medicines:

- Medicines for diabetes including tablets or insulin
- Medicines for high blood pressure
- Anticoagulants such as warfarin

When taken with Pentoxifylline, the following medicines increase the chance of you getting side effects:

- Ketorolac used for pain relief
- Theophylline used to treat wheezing or difficulty in breathing
- Ciprofloxacin used to treat bacterial infections
- Medicines used to stop blood clots from forming
- Cimetidine used to treat heartburn and stomach ulcers

Taking Pentoxifylline with food and drink

Take Pentoxifylline with or just after meals.

Pregnancy and breast-feeding

You should not take Pentoxifylline if you are pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking Pentoxifylline. This is because very small amounts may pass into the mothers' milk.

Driving and using machines

You may feel dizzy while taking this medicine. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE PENTOXIFYLLINE

Always take Pentoxifylline exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Take with or just after a meal

Adults including the elderly

The usual starting dose is 1 tablet (400mg) three times a day. Your doctor may lower your dose to 1 tablet twice a day.

Patients with kidney problems

Your doctor may give you a lower dose if necessary.

Children

Pentoxifylline is not suitable for use in children.

If you take more Pentoxifylline than you should

If you take more tablets than you should, talk to a doctor or go to a hospital straight away. The following effects may happen: low blood

pressure, feeling sleepy, fits (seizures) or uneven heartbeat.

If you forget to take Pentoxifylline

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

If you stop taking Pentoxifylline

Keep taking Pentoxifylline until your doctor tells you to stop taking it.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pentoxifylline can cause side effects, although not everybody gets them.

Stop taking Pentoxifylline and see your doctor or go to a hospital straight away if;

- If you have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Bleeding under the skin
- Blood in your vomit or stools (motions)
- If you develop a condition called aseptic meningitis. Signs include headache, neck stiffness, eye pain or discomfort in bright light

Tell your doctor as soon as possible if you have any of the following side effects:

- You bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia).
- Increased or fast heart beat (tachycardia)
- Chest pain (angina)
- Irregular heart beat (palpitations)
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- You get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia)

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet:

- Feeling sick (nausea) or being sick (vomiting), diarrhoea
- Headache, feeling dizzy, light-headed or faint
- Flushing
- Feeling agitated, sleep problems
- An illness where the removal of bile from the liver is blocked (intrahepatic cholestasis). Signs include jaundice, rash or fever, and the colour of your water (urine) becomes darker
- Discomfort or bloating in the abdomen
- Rash
- Constipation
- Producing more saliva than usual

Blood tests

Pentoxifylline can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

United Kingdom

5. HOW TO STORE PENTOXIFYLLINE

Keep out of the reach and sight of children.

Do not use Pentoxifylline after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use Pentoxifylline if you notice your tablets are crumbling, broken or discoloured.

Do not store above 25°C. Store in the original package.

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.

6. FURTHER INFORMATION

What Pentoxifylline contains

a) Each film coated tablet contains:

Pentoxifylline USP 400mg

Excipients q.s.

The other ingredients are hydroxyethyl cellulose, povidone, talc, magnesium stearate, hypromellose, macrogol 8000, erythrosine, and titanium dioxide

What Pentoxifylline looks like and contents of the pack

PVC/PVDC/Al blisters.

Pack sizes: Blisters: 7, 14, 28, 30, 50, 90, 100 and 500mg modified-release tablets.

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

Mumbai, India
Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.

Customer Service and Product Inquiries:
1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: tajgroup@tajpharma.com