

Package leaflet: Information for the user

Pentoxifylline 400mg Modified Release Tablets

Pentoxifylline

Is this leaflet hard to see or read? Phone 0118 211 4039 for help

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 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. See section 4.

What is in this leaflet:

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

1. What Pentoxifylline is and what it is used for

The name of this medicine is Pentoxifylline 400mg Modified Release Tablets (called Pentoxifylline throughout this leaflet).

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.

This medicine 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. What you need to know before you take Pentoxifylline

Do not take this medicine if:

- You are allergic (hypersensitive) to pentoxifylline, other similar medicines such as theophylline or aminophylline or to any of the other ingredients of Pentoxifylline (listed in section 6)
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 this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this 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 this medicine.

Other medicines and Pentoxifylline

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Pentoxifylline with food and drink

Take this medicine with or just after meals.

Pregnancy and breast-feeding

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

You should not take this medicine if you are pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking this medicine. 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.

Pentoxifylline contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Pentoxifylline

Always take this medicine exactly as your doctor has told you. 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.

Use in children

This medicine 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 this medicine until your doctor tells you to stop taking it.

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

4. Possible side effects

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

Stop taking this medicine 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

This medicine 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

You can also report side effects directly via the Yellow Card Scheme

at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pentoxifylline

Keep out of the sight and reach of children.

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

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

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What this medicine contains

- Each tablet contains 400mg of the active substance, pentoxifylline
- The other ingredients are hydroxyethyl cellulose, povidone, talc, magnesium stearate, hypromellose, macrogol 8000, erythrosine (E127), and titanium dioxide (E171)

What this medicine looks like and contents of the pack

The tablets are oblong in shape and coloured pink, with “ATA” stamped on one side. The tablets are available in blister packs of 90 tablets.

Marketing Authorisation Holder and ManufacturerMarketing Authorisation Holder

Neuraxpharm UK Limited
Suite 2, Arlington Flex, Third Floor
Building 1420, Arlington Business Park,
Theale, Reading,
Berkshire RG7 4SA
United Kingdom

Manufacturer

Sanofi S.r.l.
Strada Statale 17, Km 22
67019 Scoppito (L'Aquila)
Italy

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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