

Trental® 400 mg modified-release tablets

(pentoxifylline)

3402
29.02.24[3]

PATIENT INFORMATION LEAFLET

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.

Your medicine is available using the above name but it will be referred as Trental throughout the leaflet

In this leaflet:

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

1. WHAT TRENTAL IS AND WHAT IT IS USED FOR

Trental 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.

Trental 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 TRENTAL

Do not take Trental if:

- You are allergic (hypersensitive) to pentoxifylline, other similar medicines such as theophylline or aminophylline or to any of the other ingredients of Trental (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 Trental.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trental 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 Trental.

Other medicines and Trental

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 Trental can affect the way some other medicines work. Also some medicines can affect the way Trental works.

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

Trental 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 Trental, 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

Trental with food and drink

Take Trental with or just after meals.

Pregnancy and breast-feeding

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

You should not take Trental if you are pregnant.

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

Trental 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 TRENTAL

Always take Trental 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.

Use in children

Trental is not suitable for use in children.

If you take more Trental 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 Trental

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

If you stop taking Trental

Keep taking Trental 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, Trental can cause side effects, although not everybody gets them.

Stop taking Trental 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

Trental 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. 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 TRENTAL

Keep out of the sight and reach of children.

Do not use Trental 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 Trental 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 Trental contains

- Each tablet contains 400 mg of pentoxifylline in a modified release form.
- The other ingredients are hydroxyethyl cellulose, povidone, talc, magnesium stearate, hypromellose, titanium dioxide (E171), erythrosine (E127), macrogol 8000 and purified water.

What Trental looks like and contents of the pack

Trental are oblong shaped, pink, modified release tablets marked 'ATA' on one side and plain on the reverse.

The tablets are available in pack of 60 and 90 tablets.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by

Sanofi S.r.l, Strada Statale 17, km 22, 67019 Scoppito (AQ), Italy.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD.
Repackaged by Servipharm Ltd.

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PL 20636/3402

Leaflet issue and revision date (Ref): 29.02.24[3]

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