

Trental[®] 400

Oxypentifylline

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Trental 400.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Trental 400 is used for

Trental 400 is a type of medicine used to improve the circulation of the blood.

Trental 400 is used to treat the symptoms of a condition called chronic occlusive arterial disease. Symptoms of this disease can include lameness and pain, usually in the leg muscles.

Trental 400 is a slow release tablet, which means that the active ingredient is released slowly over several hours.

Your doctor, however, may prescribe Trental 400 for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take Trental 400 if you have:

- had a recent operation
- bleeding problems
- heart problems, such as having suffered a heart attack
- kidney or liver problems
- stomach ulcers or a history of stomach ulcers
- had an allergic reaction to caffeine or theophylline (a medicine used to treat asthma)

Do not take Trental 400 if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Trental 400 to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Do not take it if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

Do not take it if you are breastfeeding or planning to breastfeed.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

**any of the ingredients listed at the end of this leaflet
any other medicines including caffeine or theophylline (a medicine used to treat asthma)
any other substances, such as foods, preservatives or dyes.**

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Trental 400 is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor or pharmacist if you are breastfeeding or planning to breastfeed.

Trental 400 passes into breast milk and there is a possibility your baby may be affected. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney or liver problems
- problems with your blood pressure
- problems with your heart eg. an irregular or rapid heart beat

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Trental 400.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may interfere with how Trental 400 works. These include:

- warfarin and other medicines used to stop blood clots.
- medicines used to treat high blood pressure
- theophylline, a medicine used to treat asthma
- some medicines used to treat diabetes
- some medicines used to treat the symptoms of cough and colds

These medicines may be affected by Trental 400, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Trental 400.

How to take it

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines. The usual dosage is one tablet three times a day.

The standard dose for this medicine is one tablet three times a day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Trental 400 may not work as well and your problem may not improve.

How to take it

Swallow the tablet whole with a full glass of water or other liquid.

Do not crush or chew the tablets. Each Trental 400 tablet has been especially designed to slowly release the right dose of medicine. If you crush, chew or divide Trental 400 tablets they will not work properly.

When to take it

Take Trental 400 during or immediately after a meal, at about the same time each day. If you take it on an empty stomach, it may cause stomach upset.

Take Trental 400 at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

The medicine helps control your condition, but it does not cure it. Therefore, you must take it every day.

Trental 400 can take time to work. Your symptoms may improve within 2-4 weeks, however it can take up to 8 weeks to take effect.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and

take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Trental 400.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Trental 400, you may feel flushed, light-headed or dizzy, drowsy or you may also feel faint.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Trental 400.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Trental 400.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, stop

taking it and tell your doctor or pharmacist immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Trental 400, or lower the dosage, without checking with your doctor.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Trental 400 affects you.

It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Trental 400.

It helps most people, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting or an upset stomach
- feeling bloated
- diarrhoea or constipation
- dizziness
- headache
- problems sleeping
- blurred vision
- drowsiness
- rash

These are mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following:

- tremor
- bleeding or bruising more easily than normal
- yellowing of the skin and eyes (jaundice)

These may be serious side effects of Trental 400. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Trental 400. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Trental 400, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Trental 400 – oblong, pink, film-coated tablets with ‘ATA’ on one side.

Trental 400 is available in boxes of 50 tablets.

Ingredients

Active Ingredient:

Trental 400 – 400 mg oxpentifylline
per tablet

Inactive Ingredients:

- hydroxyethylcellulose
- povidone
- talc- purified
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 8000
- erthyrosine

Trental does not contain gluten,
sucrose, lactose, tartrazine or any
other azo dyes.

Manufacturer/Sponsor

Trental 400 is made in Italy.

Trental 400 is supplied in Australia
by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Trental 400 is supplied in New
Zealand by:

sanofi –aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

This leaflet was prepared in May
2008.

Australian Register Number(s)

AUST R 81197

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