Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Trental 400?

Trental 400 contains the active ingredient pentoxifylline. Trental 400 is used to improve the circulation of the blood.

For more information, see Section <u>1. Why am I using</u> <u>Trental 400?</u> in the full CMI.

2. What should I know before I use Trental 400?

Do not use if you have ever had an allergic reaction to Trental 400, caffeine, theobromine theophylline or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before I use Trental 400?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Trental 400 and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use Trental 400?

- The standard dose is one tablet three times a day. Your doctor may have prescribed a different dose.
- Take Trental 400 at about the same time each day. Take the tablet during or immediately after a meal.
- Swallow the tablet whole with a full glass of water or other liquid. Do not crush or chew the tablets.

More instructions can be found in Section <u>4. How do I</u> <u>use Trental 400?</u> in the full CMI.

5. What should I know while using Trental 400?	
Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Trental 400.

	 If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist straight away.
Things you should not do	 Do not stop taking Trental 400, or lower the dosage, without checking with your doctor.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Trental 400 affects you. Trental 400 may cause dizziness or light- headedness in some people, especially after the first dose.
Looking after your medicine	 Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C. Keep your tablets in the blister pack until it is time to take them.

For more information, see Section <u>5. What should I know</u> while using Trental 400? in the full CMI.

6. Are there any side effects?

Common side effects include nausea, vomiting or an upset stomach, indigestion, diarrhoea, dizziness, headache, problems sleeping, blurred vision, and drowsiness. Serious side effects include bleeding or bruising more easily than normal, yellowing of the skin and eyes (jaundice), tremor, and symptoms of an allergic reaction, which include swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing. For more information, including what to do if you have any side effects, see Section <u>6. Are there any</u> <u>side effects?</u> in the full CMI.

Trental® 400

Active ingredient: pentoxifylline

Consumer Medicine Information (CMI)

This leaflet provides important information about using Trental 400. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Trental 400.

Where to find information in this leaflet:

- 1. Why am I using Trental 400?
- 2. What should I know before I use Trental 400?
- 3. What if I am taking other medicines?
- 4. How do I use Trental 400?
- 5. What should I know while using Trental 400?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Trental 400?

Trental 400 contains the active ingredient

pentoxifylline. 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.

2. What should I know before I use Trental 400?

Warnings

Do not use Trental 400 if:

• you are allergic to pentoxifylline, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have allergies to any other substances, such as foods, preservatives or dyes
- have any other 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
- take any medicines for any other condition
- plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

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.

Children and adolescents

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Trental 400 and affect how it 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
- ciprofloxacin
- cimetidine, a medicine used to treat reflux and ulcers

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Trental 400.

4. How do I use Trental 400?

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 standard dose for this medicine is one tablet three times a day. Your doctor may have prescribed a different dose.
- Follow the instructions provided and use Trental 400 until your doctor tells you to stop.

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 Trental 400

- Trental 400 should be taken during or immediately after a meal. 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.
- As your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take Trental 400

Trental 400 should be taken regularly at the same time each day. If you miss your dose at the usual time, do not try to make up for missed doses by taking more than one dose at a time. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you 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 use too much Trental 400

If you think that you have used too much Trental 400, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 POISON or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using Trental 400?

Things you should do

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

Remind any doctor, dentist or pharmacist you visit that you are using Trental 400.

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

Call your doctor straight away if you:

 become pregnant while you are taking this medicine, and stop taking it.

Things you should not do

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Trental 400 affects you.

Trental 400 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

• 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Gut-related: nausea, vomiting or an upset stomach indigestion feeling bloated, burping or passing wind diarrhoea or constipation Head-related: dizziness 	Speak to your doctor if you have any of these less serious side effects and they worry you. These are mild side effects of this medicine and usually short-lived.

Less serious side effects	What to do
headache	
 problems sleeping 	
 blurred vision 	
 drowsiness 	
Skin-related:	
• rash	

Serious side effects

Serious side effects	What to do
 Bleeding-related: bleeding or bruising more easily than normal Liver-related: yellowing of the skin and eyes (jaundice) 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Nerve/muscle-related:tremor	Serious side effects are uncommon.
Allergic reaction-related:	
 swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing 	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Trental 400 contains

Active ingredient (main ingredient)	400 mg pentoxifylline per tablet
Other ingredients	hyetellose
(inactive ingredients)	povidone

	purified talc magnesium stearate hypromellose titanium dioxide macrogol 8000 erythrosine
Potential allergens	Trental does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Trental 400 looks like

Trental 400 - oblong, pink, film-coated tablets with 'ATA' on one side.

Trental 400 is available in boxes of 50 tablets (Aust R 81197).

Who distributes Trental 400

Trental 400 is distributed in Australia by:

Clinect Pty Ltd

120 – 132 Atlantic Drive

Keysborough VIC 3173

Australia

Free Call Australia: 1800 899 005

Trental 400 is distributed in New Zealand by:

Clinect NZ Pty Limited

C/- Ebos Group Limited

108 Wrights Road

Christchurch 8024

New Zealand

Free Call New Zealand: 0800 138 803

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