

Tramal[®] oral drops

Tramadol hydrochloride: 100 mg is contained in each mL of the solution

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

This leaflet answers some common questions about Tramal[®] oral drops. 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 it is expected to have for you.

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

Keep this leaflet. You may need to read it again.

What Tramal[®] oral drops is used for

Tramal[®] oral drops are used to relieve moderate to severe pain. This medicine belongs to a group of medicines called analgesics (pain relievers).

Your doctor may have prescribed Tramal[®] oral drops for another reason. Ask your doctor why this medicine has been prescribed for you.

Tramal[®] oral drops are not usually addictive. However, rarely, addiction to tramadol has been reported.

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

NOTE: Tramal[®] oral drops are for use in adults and children over 12 years of age. There is not enough information to recommend the use of this

medicine for children under the age of 12 years.

Before you use Tramal[®] oral drops

When you must not use this medicine

Do not take Tramal[®] oral drops if you:

- know you have an allergy to Tramal[®] oral drops or any of the ingredients listed at the end of this leaflet.
- know you have an allergy to any other medicines known as opioid analgesics e.g. morphine or codeine.
- are taking medicine for depression containing a "monoamine oxidase inhibitor" (such as Nardil[®], Parnate[®]), or have taken one within the past two weeks.

Do not take Tramal[®] oral drops

- **after the expiry date printed on the pack or**
- **if the packaging is torn or shows signs of tampering.**

If it is after the expiry date, or the packaging is damaged, return it to your pharmacist for disposal.

Tramal[®] oral drops are for use in adults and children over 12 years of age.

Do not give Tramal[®] oral drops to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you:

1. know you are sensitive to opioids.
2. have liver or kidney disease.
3. have ever had epilepsy (fits).
4. have or have had in the past dependency problems with alcohol or any drugs.
5. have sleep-related breathing disorders.
6. are pregnant or intend to become pregnant. Tramal[®] oral drops are not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using Tramal[®] oral drops during pregnancy.
7. are breast-feeding or plan to breast-feed. Tramal[®] oral drops are not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using Tramal[®] oral drops when breast-feeding.
8. have hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

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 shop. Some

medicines may interfere with Tramal® oral drops.

These include:

- carbamazepine (eg. Tegretol®)
- coumarin derivatives (eg. warfarin: some brand names are Coumadin® or Marevan®)
- medicine for irregular or rapid heart beat.
- medicines for depression, sleeplessness or mental or psychiatric conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-noradrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, quinidine, phenothiazines or antipsychotics.
- some antibiotics.

These medicines may be affected by Tramal® oral drops or may affect how well they work. You may need different amounts of your medicines, or you may need to take different medicines. Other interactions not listed above may also occur.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Tramal® oral drops

Carefully follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

Tramal® oral drops are for use in adults and children over the age of 12 years.

Do not give Tramal® oral drops to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established

The recommended dose of Tramal® oral drops is shown in the following table.

Table 1

Pack type and size	Dosage	How often?
10mL Dropper	From 20 up to 40 drops	Every 4 to 8 hours

For moderate pain, you should take a single dose of Tramal® oral drops as:

- 20 drops.
- This gives 50 mg tramadol hydrochloride.

If there is no pain relief after 30 to 60 minutes, you may take a second dose of Tramal® oral drops as:

- 20 drops.

For severe pain, you should take a single dose of Tramal® oral drops as:

- 40 drops.
- This gives 100 mg tramadol hydrochloride.

In any 24-hour period, do not take more than a maximum of 400mg tramadol hydrochloride.

400mg tramadol hydrochloride is equivalent to:

- a total of 160 drops (8x20 drops, or 4x 40 drops).

If you are older than 75 years of age, you may require a lower dose of Tramal® oral drops.

The analgesic effect lasts for 4 to 6 hours. The length of time varies according to the pain being treated.

How to take it

Follow your doctor's directions or refer to "How much to take" section of this document.

The 10mL bottle has a built-in dropper and child-resistant screw cap.

To open the bottle

- press down firmly on the cap.
- then unscrew the cap.

To obtain the drops

- turn the bottle upside down
- tap lightly on the base of the bottle, until the first drops appear.
- accurately count out the correct number of drops into a medicine measure.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Carefully follow all directions given to you by your doctor and the pharmacist. These directions may differ from the information contained in this leaflet.

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

If you forget to take it

If you forget to take a dose, you can take it as soon as you remember. The next dose should be taken after 4

to 6 hours or as prescribed by your doctor.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

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

If you take too much (overdose)

- If you think that you or anyone else may have taken too much of this medicine:
- **immediately telephone for advice from your doctor or the Poisons Information Centre (in Australia 13 11 26) or go to your nearest Hospital, Accident and Emergency Department Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

Symptoms of an overdose may include:

- breathing difficulty
- fits or convulsions.

While you are using Tramal® oral drops

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If your pain is not severe and you feel that you do not need as much of the Tramal® oral drops as your doctor prescribed, consult your doctor.

Tell your doctor if your pain gets worse. Do not take extra doses without checking with your doctor.

Tell any other doctors, dentists, and pharmacists who treat you, that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

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

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist if you have any unpleasant effects while you are taking Tramal® oral drops even if you do not think the effect is connected with the medicine or is not listed in this leaflet.

Like all medicines, Tramal® oral drops can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

The most common side-effects are:

- dizziness
- sedation, fatigue
- headache
- constipation
- nausea, vomiting
- sweating
- dry mouth.

The following side-effects are less common:

- indigestion
- changes in appetite
- skin reactions
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor
- seizures
- respiratory depression
- improvement in mood
- confusion
- sleep disturbance
- blurred vision
- difficulty in passing urine
- Serotonin Syndrome: signs of this vary and are not specific: they may include sweating, agitation, muscle twitching, spontaneous muscle contraction, tremor, high body temperature. Serotonin Syndrome may

result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.

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

- skin rash (red spots or patches), itching hives, skin lumps
- swelling or puffiness of the eyelids, face or lips
- chest tightness, wheezing or pain in the chest
- heart palpitations, faintness or collapse
- hallucinations
- convulsions

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

Other side effects not listed above may also occur in some people.

Can Tramal® oral drops be addictive?

When used as prescribed by the doctor, addiction to Tramal® oral drops is unlikely.

If you are taking Tramal® oral drops for a prolonged period of time, your body may become used to the medicine and mild withdrawal symptoms may occur if you suddenly stop taking the medicine.

Take Tramal® oral drops only as directed by your doctor. Do not suddenly stop taking Tramal® oral drops. Your dosage may need to be reduced gradually.

After using Tramal® oral drops

Storage

Store Tramal® oral drops at a temperature below 30°C.

Protect from light.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep Tramal® oral drops where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use Tramal® oral drops after the expiry date on the package.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any Tramal® oral drops that is left over.

Product description

What it looks like

Tramal® oral drops are a clear solution.

They come in a 10mL bottle with built-in dropper.

Ingredients

The active ingredient of Tramal® oral drops is tramadol hydrochloride. There is 50mg tramadol hydrochloride in 0.5mL (20 drops) of Tramal® oral drops. Tramal® oral drops also contain:

- potassium sorbate
- glycerol
- propylene glycol
- sucrose
- sodium cyclamate

- saccharin sodium
- ethoxylated hydrogenated castor oil
- mint oil, partly dementholised
- aniseed flavour (87122)
- purified water.

The Australian Registration Number is AUST R 99001.

This is not all the information available on Tramal® oral drops. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Sponsor

Tramal® oral drops are made in Germany by Grunenthal GmbH and supplied in Australia by:

Seqirus Pty Ltd
ABN 26 160 735 035
63 Poplar Rd
Parkville 3052 VIC
AUSTRALIA

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