

## Tramal® oral drops

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

### Consumer Medicine Information

#### WARNING

##### Limitations of use

TRAMAL® oral drops should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

##### Hazardous and harmful use

TRAMAL® oral drops poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

##### Life threatening respiratory depression

TRAMAL® oral drops can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting TRAMAL® oral drops and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

##### Use of other medicines while using TRAMAL® oral drops

Using TRAMAL® oral drops with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using TRAMAL® oral drops.

#### 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 are used for

Tramal® oral drops are used to relieve severe pain. This medicine belongs to a group of medicines called opioid 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.

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

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

It should not be used in children under the age of 12 years or following the removal of tonsils and/or adenoids in people under 18.

#### Before you use Tramal® oral drops

##### When you must not use this medicine

##### Do not take Tramal® oral drops if you:

- have an allergy to Tramal® oral drops or any of the ingredients listed at the end of this leaflet.
- have an allergy to any other medicines known as opioid analgesics e.g. morphine or codeine.
- you have respiratory disease or slow or shallow breathing
- you have taken large amounts of alcohol or other substances which can affect your level of consciousness. Some examples of these substances include sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)

- are taking a medicine for depression containing a "monoamine oxidase inhibitor" also known as a MAOI or have taken one within the past two weeks. Examples of MAOI-containing medicines are Nardil®, Parnate®
- have uncontrolled epilepsy or if your epilepsy is not well controlled by treatment
- are younger than 12 years old or if you are between 12 –18 years of age and are recovering from an operation to remove your tonsils and/or adenoids.

##### 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.

##### Addiction

You can become addicted to Tramal® oral drops even if you take it exactly as prescribed. Tramal® oral drops may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

##### Dependence

As with all other opioid containing products, your body may become used to you taking Tramal® oral drops. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Tramal® oral drops suddenly, so it is important to take it exactly as directed by your doctor.

##### Tolerance

Tolerance to Tramal® oral drops may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

##### Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea

- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Very rarely, some patients have experienced the following withdrawal reactions:

- panic attacks
- severe anxiety
- hallucinations
- tingling or numbness (pins and needles)
- ringing in your ears
- confusion, delusions or paranoia.

Tramal® oral drops given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

**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:

- know you are sensitive to opioids
- you drink alcohol
- have any health problems including:
  - any lung or breathing problems
  - sleep-related breathing disorders
  - fits or convulsions, or take medicines for epilepsy
  - any disorder of the kidney or liver
  - any stomach problems
  - a severe headache or feel sick due to a head injury
- have or have had drug or alcohol dependency problems
- have hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency
- are pregnant or intend to become pregnant. Tramal® oral drops are not recommended for use during pregnancy. TRAMAL® can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using Tramal® oral drops during pregnancy
- 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

**If you have not told your doctor about any of the above, tell them 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 heartbeat.
- 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 Tramal® oral drops.

### **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 12 years of age.**

It should not be used in children under the age of 12 years or following the removal of tonsils and/or adenoids in people under 18.

The following table provides a summary of the recommended dose of Tramal® oral drops and how often to take them.

**Table 1**

Pack type and size	Dosage	How often?
10 mL Dropper	From 20 up to 40 drops	Every 4 to 6 hours

The recommended dose of Tramal® oral drops is:

- 20 drops.

This gives 50 mg tramadol hydrochloride and should be taken as a single dose.

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

- 20 drops.

For more 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 400 mg tramadol hydrochloride.

400 mg tramadol hydrochloride is equivalent to:

- a total of 160 drops (8x20 drops, or 4x40 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*

You can take Tramal® oral drops at any time of the day. It does not matter if you take this medicine before or after food.

### *How long to take it*

This differs between individuals depending on how severe your pain is, how you respond to Tramal® oral drops, and the cause of your pain. Ask your doctor for advice on how long you need to take Tramal® oral drops.

**Carefully follow all directions given to you by your doctor and the pharmacist.**

These directions may differ from the information contained in this leaflet.

**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 or someone else receive too much (overdose), and experience one or more of the symptoms below, call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Tramal® oral drops that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat

- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have taken too much Tramal® oral drops, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

### **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 as 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 is not helped or gets worse. Do not take increased amounts or 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 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. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

**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
- hiccups
- 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.
- low blood glucose (hypoglycaemia)

**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

Talk to your doctor if you experience any of the following symptoms while taking TRAMAL®:

Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels).

Adrenal insufficiency is caused by failure of the adrenal glands to produce enough or any of the hormones cortisol and aldosterone.

If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

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

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

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## After using Tramal® oral drops

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### Storage

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

Discard 12 months after opening.

**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.

### Disposal

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.

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## Product description

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### What it looks like

Tramal® oral drops are a clear solution.

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

### Ingredients

The active ingredient of Tramal® oral drops is tramadol hydrochloride. There is 50 mg 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 Grünenthal GmbH and sponsored in Australia by:

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