

TRAMAL® ORAL DROPS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I taking TRAMAL® ORAL DROPS?

TRAMAL® ORAL DROPS contain the active ingredient tramadol hydrochloride. TRAMAL® ORAL DROPS are used to relieve severe pain.

For more information, see Section [1. Why am I taking TRAMAL® ORAL DROPS?](#) in the full CMI.

2. What should I know before I take TRAMAL® ORAL DROPS?

Do not take if you have ever had an allergic reaction to TRAMAL® ORAL DROPS, other opioids 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 [2. What should I know before I take TRAMAL® ORAL DROPS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRAMAL® ORAL DROPS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TRAMAL® ORAL DROPS?

Your doctor will tell you the dosage of TRAMAL® ORAL DROPS to take. Follow the instructions given by your doctor carefully.

More instructions can be found in Section [4. How do I take TRAMAL® ORAL DROPS?](#) in the full CMI.

5. What should I know while taking TRAMAL® ORAL DROPS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TRAMAL® ORAL DROPS.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• If you become pregnant while taking this medicine, tell your doctor immediately.• Tell your doctor if your pain is not helped or gets worse.• If you are about to have any blood tests, tell your doctor that you are taking TRAMAL® ORAL DROPS.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• 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 using this medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Avoid driving, operating heavy machinery until you know how this medicine affects you. TRAMAL® ORAL DROPS 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.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are using this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store in a cool, dry place, below 30°C.

For more information, see Section [5. What should I know while taking TRAMAL® ORAL DROPS?](#) in the full CMI.

6. Are there any side effects?

TRAMAL® ORAL DROPS may cause constipation, nausea, vomiting, indigestion, changes in appetite, hiccups, dry mouth, dizziness, headache, fatigue and sweating.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice: loss of consciousness, breathing changes (slow or shallow breathing), or signs of allergic reaction (skin rash (red spots or patches), itching, shortness of breath, swelling of the face, lips, mouth, tongue or throat). TRAMAL® ORAL DROPS poses risk of abuse, misuse and addiction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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.

TRAMAL® ORAL DROPS

Active ingredient: *tramadol hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRAMAL® ORAL DROPS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TRAMAL® ORAL DROPS.**

Where to find information in this leaflet:

- [1. Why am I taking TRAMAL® ORAL DROPS?](#)
- [2. What should I know before I take TRAMAL® ORAL DROPS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take TRAMAL® ORAL DROPS?](#)
- [5. What should I know while taking TRAMAL® ORAL DROPS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking TRAMAL® ORAL DROPS?

TRAMAL® ORAL DROPS contains the active ingredient **tramadol hydrochloride**. Tramadol hydrochloride belongs to a group of medicines called opioid analgesics.

TRAMAL® ORAL DROPS are used to relieve severe pain.

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 years.

TRAMAL® ORAL DROPS is available only with a doctor's prescription.

2. What should I know before I take TRAMAL® ORAL DROPS?

Warnings

Do not use TRAMAL® ORAL DROPS if:

- you are allergic to tramadol hydrochloride, or any of the ingredients listed at the [end of this leaflet](#). Always check the ingredients to make sure you can take this medicine.
- you have an allergy or sensitivity 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 or consciousness. Some examples of these substances include sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions).
- you are taking medicine for depression containing a 'monoamine oxidase inhibitor' also known as MAOI or have taken one within the past two weeks. Examples of MAOI-containing medicines are AURORIX® (moclobemide), PARNATE® (tranylcypromine).
- you have uncontrolled epilepsy or if your epilepsy is not well-controlled by treatment
- you are younger than 12 years old or if you are between 12 – 18 years of age and are recovering from an operation to remove tonsils and/or adenoids.

Check with your doctor if you:

- 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.
- you have, or have had, any drug or alcohol dependence problems.
- have hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency
- take any medications for any other condition.

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 [6. Are there any side effects?](#)

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.

If you are not sure whether you should start taking TRAMAL® ORAL DROPS, talk to your doctor.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

You should not take TRAMAL ORAL DROPS® during pregnancy unless your doctor has told you to. Taking TRAMAL® ORAL DROPS during pregnancy may lead to withdrawal symptoms in the newborn baby.

You should not take TRAMAL® ORAL DROPS during labour as it can cause breathing problems or signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed. TRAMAL® ORAL DROPS are not recommended for use during breastfeeding.

Children

TRAMAL® ORAL DROPS are for use in adults and children over 12 years of age.

Do not give this medicine to children younger than 12 years old or people who are between 12 – 18 years of age and are recovering from an operation to remove tonsils and/or adenoids.

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 TRAMAL® ORAL DROPS and affect how it works. These include:

- carbamazepine (e.g. TEGRETOL®)
- coumarin derivatives (e.g. 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
- a group of medicines called anticholinergics. These medicines can be used to treat a wide range of medical conditions including asthma, a respiratory condition called chronic obstructive pulmonary disorder (COPD), Parkinson's Disease, cardiovascular disease, urinary incontinence (loss of bladder control), psychiatric disorders including schizophrenia, anxiety, depression, allergies and travel sickness/nausea.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRAMAL® ORAL DROPS.

4. How do I take TRAMAL® ORAL DROPS?

How much to take

Carefully follow all directions given to you by your doctor. They may differ from the information provided in this leaflet. If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

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 years.

The table below provides a summary of the recommended dose of TRAMAL® ORAL DROPS and how often to take them.

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 (8 x 20 drops, or 4 x 40 drops).

If you are over 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.

Follow the instructions provided and use TRAMAL® ORAL DROPS until your doctor tells you to stop.

How to take TRAMAL® ORAL DROPS

The 10 mL 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.

This medicine can be taken before or after food.

How to long to take TRAMAL® ORAL DROPS

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.

If you forget to use TRAMAL® ORAL DROPS

TRAMAL® ORAL DROPS should be used regularly at the same time each day.

If you miss your dose at the usual time, you can take it as soon as you remember it. The next dose should be taken after 4 to 6 hours, or as prescribed by your doctor.

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 that you missed.

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

If you take too much TRAMAL® ORAL DROPS

If you or someone else receive too much (overdose), and experiences 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
- Serotonin syndrome symptoms, sweating, agitation, muscle twitching, tremor, spontaneous muscle contraction, high body temperature.

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think that you or someone else may have used too much TRAMAL® ORAL DROPS, you may need urgent medical attention.

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.

5. What should I know while taking TRAMAL® ORAL DROPS?

Things you should do

- If you are about to start 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 to take as much 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.

Call your doctor straight away if you:

Do not feel well while taking TRAMAL® ORAL DROPS.

Things you should not do

- Do not stop taking your medicine or change the dosage without checking with your doctor.
Some people may feel unwell if they suddenly stop taking TRAMAL® ORAL DROPS. If you suddenly stop taking TRAMAL® ORAL DROPS you may experience withdrawal symptoms (see 'Withdrawal' section above).
- Do not give your medicine to anyone else, even if they seem to have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

Avoid driving, operating heavy machinery or using any machines or tools until you know how TRAMAL® ORAL DROPS affects you.

TRAMAL® ORAL DROPS 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are taking TRAMAL® ORAL DROPS.

Drinking alcohol while taking TRAMAL® ORAL DROPS may cause serious side effects such as drowsiness, breathing difficulties, and loss of consciousness.

Looking after your medicine

- Store TRAMAL® ORAL DROPS below 30°C.
- Discard 12 months after opening.

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

Store it in a cool dry place away from moisture, heat or sunlight; 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.

When to discard your medicine

If the medicine is damaged or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

Do not take this medicine after the expiry date.

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 the time they are not serious, however, sometimes they are serious and 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
Gastrointestinal and mouth related: Mild abdominal problems such as constipation, nausea, vomiting, indigestion, changes in appetite, hiccups or dry mouth. Neurological related: <ul style="list-style-type: none">• Dizziness• headache.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects (continued)	What to do
<p>General body related:</p> <ul style="list-style-type: none"> • Fatigue • Sweating • Skin reactions. <p>Sleep-related breathing disorders:</p> <ul style="list-style-type: none"> • TRAMAL® can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. <p>Sleep-related:</p> <ul style="list-style-type: none"> • Sleep disturbance. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction related:</p> <ul style="list-style-type: none"> • skin rash (red spots or patches), itching, hives, skin lumps. • swelling or puffiness of the eyelids, face or lips. <p>Heart and lung related:</p> <ul style="list-style-type: none"> • respiratory depression (slow or shallow breathing). • sudden onset of low blood pressure, collapse. • chest tightness, wheezing or pain in the chest. • heart palpitations, faintness or collapse. • low blood glucose (hypoglycaemia). <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> • sedation. • tremor, seizures or convulsions. • 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. • hallucinations • confusion. • improvement in mood. 	<p>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.</p>

Serious side effects (continued)	What to do
<p>Muscle-related</p> <ul style="list-style-type: none"> • muscle weakness. <p>Urinary system related:</p> <ul style="list-style-type: none"> • difficulty in passing urine. <p>Eye related:</p> <ul style="list-style-type: none"> • blurred vision. <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • Severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system. • Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time. <p>Hormone related:</p> <ul style="list-style-type: none"> • Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops. • Extreme fatigue, lack of appetite, weight loss, 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. 	<p>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.</p>

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 www.tga.gov.au/reporting-problems. 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 TRAMAL® ORAL DROPS contains

Active ingredient (main ingredient)	Tramadol hydrochloride. There is 50 mg tramadol hydrochloride in 0.5 mL (20 drops) of TRAMAL® ORAL DROPS.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• potassium sorbate• glycerol• propylene glycol• sucrose• sodium cyclamate• saccharin sodium• ethoxylated hydrogenated castor oil• mint oil, partly dementholised• aniseed flavour (PHL-140824)• purified water.
Potential allergens	Contains sugars, saccharin, sorbates.

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

What TRAMAL® ORAL DROPS looks like

There is one strength of TRAMAL® ORAL DROPS:
TRAMAL® ORAL DROPS 100 mg/mL oral liquid bottle (AUST R 99001)

TRAMAL® ORAL DROPS are a clear solution.

The registered pack size is a 10 mL bottle with built-in dropper.

Who distributes TRAMAL® ORAL DROPS

TRAMAL® ORAL DROPS are manufactured by Grünenthal GmbH in Germany and sponsored in Australia by:

Seqirus Pty Ltd
ABN: 26 160 735 035
655 Elizabeth Street
Melbourne VIC 3000 Australia

Telephone: 1800 642 865
www.cslseqirus.com.au

Distributor:
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This leaflet was prepared in December 2025.