

## Consumer Medicine Information (CMI) summary

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

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

### 1. Why am I taking TRAMEDO?

TRAMEDO contains the active ingredient tramadol hydrochloride. TRAMEDO is used to relieve severe pain. For more information, see Section [1. Why am I taking TRAMEDO?](#) in the full CMI.

### 2. What should I know before I take TRAMEDO?

Do not take if you have ever had an allergic reaction to tramadol hydrochloride, 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 TRAMEDO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TRAMEDO 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 TRAMEDO?

Swallow the capsules whole with a glass of water. Your doctor will decide the right dose for you. Do not take more than eight TRAMEDO capsules in 24 hours. More instructions can be found in Section [4. How do I take TRAMEDO?](#) in the full CMI.

### 5. What should I know while taking TRAMEDO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are taking TRAMEDO.</li><li>If you become pregnant or plan to breastfeed while taking TRAMEDO, tell your doctor immediately.</li><li>If your pain is not as severe or if your pain is not helped or gets worse, talk to your doctor.</li><li>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>If you have to have any blood tests, tell your doctor that you are taking this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop taking your medicine suddenly or change the dosage without checking with your doctor.</li><li>Do not give this medicine to anyone else, even if they have the same conditions as you.</li><li>Do not take this medicine to treat any other conditions unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Avoid driving, operating heavy 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 or do anything else that could be dangerous.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Drinking alcohol while taking this medicine can cause drowsiness, coma or death.</li><li>Do not drink alcohol while using this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your capsules in the pack until it is time to take them.</li><li>Keep your capsule below 30°C.</li></ul>

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

### 6. Are there any side effects?

Tell your doctor if you have these common side effects and they worry you: dizziness, sedation, fatigue, headache, constipation, nausea or vomiting, sweating or dry mouth. Seek immediate medical advice if you notice these serious side effects: 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 if you have extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. 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 for use**

TRAMEDO 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**

TRAMEDO 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**

TRAMEDO 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 TRAMEDO 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 TRAMEDO**

**Using TRAMEDO 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 TRAMEDO.

# TRAMEDO®

Active ingredient(s): *tramadol hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking TRAMEDO. **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 TRAMEDO.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking TRAMEDO?

TRAMEDO contains the active ingredient **tramadol hydrochloride**, which belongs to a group of medicines called opioid analgesics (pain relievers).

TRAMEDO is used to relieve severe pain.

TRAMEDO is 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 people who are between 12 – 18 years of age and are recovering from an operation to remove tonsils and/or adenoids.

## 2. What should I know before I take TRAMEDO?

**Warnings****Do not take TRAMEDO if:**

- you are allergic to:
  - tramadol hydrochloride
  - other medicines known as opioid analgesic, e.g. morphine or codeine
  - any of the ingredients listed at the end of this leaflet.

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

Some of the symptoms of an allergic reaction may include:

  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin.
- 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)
- you are taking medicine for depression containing a monoamine oxidase inhibitor (MAOI) or have taken a MAOI within the past two weeks. Examples of MAOI-

containing medicines are moclobemide and tranlycypromine

- 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 your tonsils and/or adenoids
- **you are lactose or galactose intolerant.**

This medicine contains lactose.

**The expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.**

If the medicine has expired or is damaged, return it to your pharmacist for disposal.

#### **Check with your doctor if you:**

- you have a known allergy to tramadol hydrochloride or any of the ingredients listed at the end of this leaflet
- you are known to be sensitive to opioids
- you drink alcohol
- you have or have had any problems with drug or alcohol dependence
- have or have had any of the following medical conditions:
  - o any lung or breathing problems
  - o sleep - related breathing disorders
  - o any condition that may affect how your kidney or liver work
  - o any stomach problems
  - o a severe headache or feel sick due to a head injury
  - o any fits or convulsions or take medicine for epilepsy
- take any medicines for any other conditions

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 TRAMEDO even if you take it exactly as prescribed. TRAMEDO 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 TRAMEDO. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking TRAMEDO suddenly, so it is important to take it exactly as directed by your doctor.

#### **Tolerance**

Tolerance to TRAMEDO 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 TRAMEDO, talk to your doctor.**

If you have not told your doctor about any of the above, tell them before you start taking TRAMEDO.

#### **Pregnancy and breastfeeding**

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

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

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

Talk to your doctor if you are breastfeeding or plan to breastfeed. TRAMEDO is not recommended for use during breastfeeding.

### **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 TRAMEDO and affect how it works. These include:**

- carbamazepine
- coumarin derivatives (e.g. warfarin)
- medicine for irregular or rapid heartbeat
- medicines for depression, sleeplessness, mental or psychiatric conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-noradrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- 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.

These medicines may be affected by TRAMEDO, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Other interactions not listed above may also occur.

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

## 4. How do I take TRAMEDO?

### How much to take

- Your doctor will decide the right dose for you. This may depend on your condition, age, other medicines you are taking and how you respond to TRAMEDO.
- An initial dose of one TRAMEDO capsule may provide sufficient pain relief, followed by one or two capsules two to three times a day as required.
- For more severe pain, two TRAMEDO capsules are usually required for the first dose, followed by one or two capsules every four to six hours as required.
- Patients over 75 years of age may require a lower daily dose.
- **Do not take more than eight TRAMEDO capsules in 24 hours.**

### How to take TRAMEDO

- Swallow the capsules whole with a glass of water.
- TRAMEDO can be taken with or without food.

### How long to take TRAMEDO for

- This differs between individuals depending on how severe your pain is, how you respond to TRAMEDO and the cause of your pain.
- Your doctor will decide how long you will take TRAMEDO for. Ask your doctor for advice on how long you need to take TRAMEDO.

### If you forget to take TRAMEDO

TRAMEDO capsules should be used regularly at the same time each day.

If you forget to take a dose, take it as soon as you remember. The next dose should then be taken after four or six 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 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 TRAMEDO

**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 TRAMEDO 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 anyone else has taken too much TRAMEDO, urgent medical attention may be needed.

### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, 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 TRAMEDO?

### Things you should do

- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking TRAMEDO.
- If your pain is not as severe and you feel that you do not need as much TRAMEDO 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.
- 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 have to have any blood tests, tell your doctor that you are taking this medicine. It may affect the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked.
- Remind any doctor, dentist or pharmacist you visit that you are taking TRAMEDO.

### Call your doctor straight away if you:

- become pregnant while taking TRAMEDO.
- do not feel well while taking TRAMEDO.

### Things you should not do

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

Some people may feel unwell if they suddenly stop taking TRAMEDO. If you suddenly stop taking TRAMEDO you may experience withdrawal symptoms (see 'Withdrawal' section above).

- Do not give this medicine to anyone else, even if they have the same conditions as you.
- Do not use this medicine to treat any other conditions 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 TRAMEDO 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.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

**You must not drink alcohol while using TRAMEDO.**

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

### Looking after your medicine

- Keep your capsules in the pack until it is time to take them.  
If you take the capsules out of the pack they may not keep well.
- Keep your capsule below 30°C.

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; for example, do not store it:

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

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

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

### Getting rid of any unwanted medicine

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

Do not take 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.

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

You may not experience any of them.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gastrointestinal and mouth related:</b></p> <ul style="list-style-type: none"> <li>• constipation</li> <li>• nausea or vomiting</li> <li>• indigestion</li> <li>• changes in appetite</li> <li>• hiccups</li> <li>• dry mouth.</li> </ul> <p><b>Neurological related:</b></p> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• headache.</li> </ul> <p><b>General body related:</b></p> <ul style="list-style-type: none"> <li>• fatigue</li> <li>• sweating</li> <li>• skin reactions.</li> </ul> <p><b>Sleep-related breathing disorders:</b></p> <ul style="list-style-type: none"> <li>• TRAMEDO 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.</li> </ul> <p><b>Sleep-related:</b></p> <ul style="list-style-type: none"> <li>• sleep disturbance.</li> </ul> <p><b>Neurological and behaviour related:</b></p> <ul style="list-style-type: none"> <li>• improvement in mood.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction related:</b></p> <ul style="list-style-type: none"> <li>• skin rash (red spots or patches), itching, hives, skin lumps</li> <li>• swelling or puffiness of the eyelids, face or lips.</li> </ul> <p><b>Heart and lung related:</b></p> <ul style="list-style-type: none"> <li>• respiratory depression (slow or shallow breathing)</li> <li>• chest tightness, wheezing or pain in the chest</li> <li>• sudden onset of low blood pressure, collapse</li> <li>• heart palpitations, faintness or collapse</li> <li>• low blood glucose (hypoglycaemia).</li> </ul> <p><b>Neurological and behaviour related:</b></p> <ul style="list-style-type: none"> <li>• sedation</li> <li>• tremor, seizures or convulsions</li> <li>• Serotonin Syndrome: signs of this vary and are not specific: they may include sweating, agitation, muscle twitching, tremor, spontaneous muscle contraction, high body temperature.</li> </ul> <p>Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.</p> <ul style="list-style-type: none"> <li>• hallucinations</li> <li>• confusion.</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>• muscle weakness.</li> </ul> <p><b>Urinary system related:</b></p> <ul style="list-style-type: none"> <li>• difficulty in passing urine.</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Difficulty swallowing, regurgitation, chest pain that is not related to your heart,</li> </ul>	<p><b>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.</b></p>

Serious side effects	What to do
<p>especially if you have been using this medicine for a long time.</p> <p><b>Hormone related:</b></p> <ul style="list-style-type: none"> <li>• Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops.</li> <li>• 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).</li> </ul> <p>Adrenal insufficiency is caused by failure of the adrenal glands to produce enough or any of the hormones cortisol and aldosterone.</p> <p>If you have these symptoms, contact your doctor.</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](http://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 TRAMEDO contains

<b>Active ingredient (main ingredient)</b>	tramadol hydrochloride 50 mg
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate microcrystalline cellulose maize starch sodium starch glycollate magnesium stearate empty gelatin capsule RM843 size 2 white OP body – brite orange OP cap (ID 11305) TekPrint SW-9008 black ink (ID 2328)

<b>Potential allergens</b>	sugars as lactose trace quantities of sulfites
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What TRAMEDO looks like**

TRAMEDO 50 mg capsules are white and orange in colour.

The capsules have "TL 50" on the white part and a Greek alpha symbol on the orange part, printed in black ink.

- AUST R 114197 (blister pack)

Each blister pack contains 20 capsules.

### **Who distributes TRAMEDO**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in March 2026.

TRAMEDO® is a Viatris company trade mark

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