

# Tramedo

contains the active ingredient tramadol hydrochloride

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some common questions about Tramedo.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Tramedo against the benefits expected for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

**The information supplied in this leaflet relates only to Tramedo 50 mg capsules.**

It is not to be used in relation to any other product, which may also contain the same active ingredient.

### What Tramedo is used for

Tramedo is used to relieve moderate to severe pain.

Tramedo belongs to a group of medicines called analgesics, also known as "pain relievers" or "pain killers".

**Ask your doctor if you have any questions about why Tramedo has been prescribed for you.**

Your doctor may have prescribed Tramedo for another reason.

Tramedo is not recommended for use in children below 12 years, as its safety and effectiveness has not been established in this age group.

Tramedo is available only with a doctor's prescription.

Tramedo is not normally addictive if taken as directed by your doctor. Some cases have been reported rarely.

### Before you take Tramedo

#### ***When you must not take it***

**Do not take Tramedo if you are:**

- \* sensitive to opioids
- \* allergic to any other medicines containing tramadol hydrochloride (eg. Tramal)
- \* allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

**Do not take Tramedo if you have uncontrolled epilepsy or if you feel your epilepsy medicine is not working properly**

**Do not take Tramedo if you are taking a monoamine oxidase inhibitor (MAOI), or have taken a MAOI within the last 14 days.**

**Stop taking MAOIs at least 14 days before starting Tramedo.**

**Ask your doctor or pharmacist if you are unsure if you are taking, or have been taking a MAOI.**

MAOIs are medicines used to treat depression and symptoms of Parkinson's disease.

**Do not take Tramedo if you:**

- \* have consumed enough alcohol to make you feel woozy or drunk
- \* feel "high" or "excited" because you have taken sedatives or sleeping pills, psychotropics (medicines that affect mood and emotions) or other pain relievers.

**Do not take this medicine if you are lactose or galactose intolerant.**

This medicine contains lactose.

**Do not take Tramedo after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

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

#### ***Before you start to take it***

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

There is very little information on the safety of Tramedo during pregnancy. Therefore, Tramedo is not recommended for use during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Tramedo is not recommended for use during breastfeeding, as it passes into breast milk and may affect your baby.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- \* severe stomach problems
- \* lung or breathing problems
- \* head injury or a condition where there is increased pressure within the head
- \* liver and/or kidney problems
- \* drug or alcohol dependence problems
- \* fits, convulsions/epilepsy or seizures.

Your doctor may want to take special care if you have any of these conditions.

**Tell your doctor if you plan to have surgery that requires a general anaesthetic.**

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

***Taking other medicines***

**Do not take Tramedo if you are taking any monoamine oxidase inhibitors (MAOIs).**

**Wait at least 14 days after stopping your MAOI before starting Tramedo.**

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

Some medicines may be affected by Tramedo, or may affect how well it works. These include:

- \* medicines that help you to sleep or treat anxiety
- \* other pain relievers
- \* medicines used to treat mental illness or psychotic conditions

- \* selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants, medicines used to treat depression and/or other conditions
- \* coumarin derivatives such as warfarin (eg. Coumadin, Marevan)
- \* carbamazepine (eg. Tegretol, Teril)
- \* quinidine (Kinidin Durules)
- \* some antibiotics
- \* ondansetron, a medicine used for the prevention and treatment of nausea and vomiting caused by surgery or by medicine to treat cancer.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

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

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**How to take Tramedo**

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**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

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

***How much to take***

The dose varies from person to person.

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.

For moderate pain, one Tramedo capsule may be enough for the first dose, followed by one or two capsules two to three times a day as required.

For moderate to 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.

**Do not take more than eight Tramedo capsules in 24 hours.**

Tramedo is not recommended for use in children below 12 years of age.

Elderly people over 75 years of age may require a lower daily dose.

***How to take it***

**Swallow the capsules whole with a glass of water.**

***When to take it***

Tramedo can be taken with or without food.

***How long to take it for***

**Keep taking Tramedo for as long as your doctor tells you to.**

Your length of treatment will depend on the medical condition for which you require Tramedo and your response to it.

***If you forget to take it***

**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.**

**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 or have any questions, ask your doctor or pharmacist.**

## ***If you take too much Tramedo (overdose)***

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Tramedo.

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much Tramedo, you may have trouble breathing, vomit, lose consciousness or have fits or seizures.

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## **While you are taking Tramedo**

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### ***Things you must do***

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking Tramedo.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Tramedo.

If you plan to have surgery (that needs a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking Tramedo.

Talk to your doctor if you feel that you do not need to take as much Tramedo as ordered, because your pain is relieved.

If you have been taking Tramedo for a prolonged period of time, your body may have become used to the medicine. If you stop taking it suddenly, you may get some unwanted side effects.

Your doctor will tell you how to gradually reduce the amount of Tramedo you are taking before stopping completely.

If you feel that your pain gets worse or is not relieved at the dose prescribed, do not take extra doses without checking with your doctor.

Your doctor will advise you on what to do.

**Visit your doctor regularly so they can check on your progress.**

### ***Things you must not do***

**Do not drive or operate machinery until you know how Tramedo affects you.**

Tramedo can cause drowsiness, dizziness or fatigue in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

**Do not use Tramedo to treat any other conditions unless your doctor tells you to.**

**Do not give Tramedo to anyone else, even if they have the same conditions as you.**

### ***Things to be careful of***

**Be careful when drinking alcohol while taking Tramedo.**

Combining Tramedo and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while being treated with Tramedo.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tramedo.**

Tramedo relieves pain in most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

**Tell your doctor if you notice any of the following and they worry you:**

- \* nausea, vomiting
- \* constipation
- \* dizziness, drowsiness, headache
- \* sweating
- \* fatigue, tiredness
- \* dry mouth.

The above list includes common and mild side effects of Tramedo.

**See your doctor as soon as possible if you notice any of the following:**

- \* confusion
- \* nervousness or feeling anxious
- \* involuntary muscle contractions
- \* difficulty in passing urine or passing no urine
- \* blurred vision
- \* symptoms of Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea, muscle spasms, unsteadiness when walking. Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of Tramedo with other medicines, such as SSRIs (see Taking other medicines section).

The above list includes serious side effects which may require medical attention.

**See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

- \* symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- \* symptoms of "shock" such as rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting

- \* fast heart beat
- \* worsening of asthma or breathing problems
- \* fainting
- \* fits or seizures
- \* seeing, hearing or feeling things that are not there (hallucinations).

The side effects listed above are very serious and may require urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects.

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

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## After taking Tramedo

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### Storage

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

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

**Keep your capsules in the pack until it is time to take them.**

If you take the capsules out of the bottle they will not keep well.

**Keep your capsules in a cool dry place where the temperature stays below 30 degrees C.**

**Do not store Tramedo or any other medicine in the bathroom or near a sink.**

**Do not leave Tramedo in the car or on window sills.**

Heat and dampness can destroy some medicines.

### Disposal

**If your doctor tells you to stop taking Tramedo, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it 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.

Each blister pack and bottle contains 20 capsules.

### Ingredients

The active ingredient in Tramedo is tramadol hydrochloride.

Each Tramedo capsule contains 50mg of tramadol hydrochloride.

The capsules also contain the following inactive ingredients:

- \* lactose
- \* microcrystalline cellulose
- \* maize starch
- \* sodium starch glycollate
- \* magnesium stearate
- \* titanium dioxide E171
- \* TekPrint SW-9008 Black Ink
- \* colours
  - sunset yellow FCF CI15985 (E110)
  - quinoline yellow CI47005 (E104)
  - allura red AC CI16035 (E129).

Tramedo capsules are gluten free.

### Manufacturer

Tramedo is made in Australia by:

**Alphapharm Pty Limited**

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

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

Medical Information

Phone: 1800 028 365

Australian registration numbers:

AUST R 114197 (blister pack)

AUST R 114181 (bottle)

This leaflet was prepared on

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