

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.

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:

- have a known allergy to tramadol
- have an allergy to other medicines known as opioid analgesic, e.g. morphine or codeine
- have a known allergy to any of the ingredients listed at the end of this leaflet
- are taking medicine for depression containing a monoamine oxidase inhibitor (MAOI) or have taken a MAOI within the past two weeks.

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.

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

This medicine contains lactose.

Do not take this medicine 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 known to be sensitive to opioids.

Tell your doctor if you drink alcohol every day.

Tell your doctor if you have or have had any of the following medical conditions:

- any lung or breathing problems
- any diseases of the kidney, liver or pancreas
- severe stomach problems
- a serious head injury
- any fits or convulsions/epilepsy
- drug or alcohol dependence

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

Tramedo is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using Tramedo 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.

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

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

Taking other medicines

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

Some medicines and Tramedo may interfere with each other. These include:

- carbamazepine (e.g. Tegretol[®])
- coumarin derivatives (e.g. warfarin: Some brand names are Coumadin[®], or Marevan[®])
- medicine for irregular or rapid heart beat
- medicines for depression, sleeplessness or mental 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.

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.

How to take Tramedo

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.

Moderate Pain Relief:

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

Moderate to Severe Pain Relief:

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 (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, lose consciousness or have fits or seizures.

While you are taking Tramedo

Things you must do

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tramedo.

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

If you are going to have surgery (including dental surgery), tell the surgeon or anaesthetist that you are taking this medicine.

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.

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.

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 this medicine to treat any other conditions unless your doctor tells you to.

Do not give this medicine 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.

Side effects

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:

Common side effects:

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

Less common side effects:

- 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, tremor, spontaneous muscle contraction, high body temperature. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.

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

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

- 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.

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.

After taking Tramedo

Storage

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

If you take the capsules out of the pack/bottle they may not keep well.

Keep your capsule in a cool dry place where the temperature stays below 30°C.

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

Heat and dampness can destroy some medicines.

Keep it 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.

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 medicine that is left over.

Product description

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 50 mg of tramadol hydrochloride.

The capsules also contain the following inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- magnesium stearate
- titanium dioxide E171
- gelatin
- 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)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

AUST R 114197 (blister pack)

AUST R 114181 (bottle)

This leaflet was prepared on

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