

TRAMEDO®

tramadol hydrochloride capsules

CONSUMER MEDICINE INFORMATION

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.

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, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What TRAMEDO is used for

TRAMEDO is used to relieve severe pain and belongs to a group of medicines called opioid analgesics (pain relievers).

Your doctor may have prescribed TRAMEDO for another reason. Ask your doctor why TRAMEDO has been prescribed for you.

TRAMEDO is available only with a doctor's prescription.

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 following the removal of tonsils and/or adenoids in people under 18.

Before you take TRAMEDO

When you must not take it

Do not take TRAMEDO if you:

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

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.

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.

TRAMEDO 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 TRAMEDO, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you have a known allergy to tramadol 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 of the following medical conditions:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - any condition that may affect how your kidney or liver work
 - any stomach problems
 - a severe headache or feel sick due to a head injury
 - any fits or convulsions or take medicine for epilepsy
- you have or have had any problems with drug or alcohol dependence
- you are pregnant or plan to become pregnant. TRAMEDO is not recommended for use during pregnancy. TRAMEDO can pass to your unborn baby when you are

pregnant. Talk to your doctor about the risks and benefits of using TRAMEDO during pregnancy.

- you are breastfeeding or plan to breastfeed. TRAMEDO is not recommended for use during breastfeeding. Talk to your doctor about the risks and benefits of using TRAMEDO when breastfeeding.

If you have not told your doctor about any of the above, tell them 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 may interfere with TRAMEDO. 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.

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.

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

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.

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

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, 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 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

If you think you or someone else may have taken too much TRAMEDO, 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 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, 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.

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 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.

Things you must not do

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.

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 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
- 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, 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.

Tell your doctor immediately if you experience any the following side effects, as urgent medical treatment may be required:

- 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 TRAMEDO:

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 if you notice anything else that is making you feel unwell.

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 medicines 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.

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 contains sugars as lactose and traces of galactose and sulfites.

Supplier

TRAMEDO is made in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration numbers:

AUST R 114197 (blister pack)

AUST R 114181 (bottle)

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TRAMEDO[®] is a Viatris company trade mark

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