

TRAMEDO



Tramadol (as hydrochloride) 50mg capsule

What is in this leaflet

This leaflet answers some common questions about TRAMEDO. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking TRAMEDO against the benefits they expect it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

What TRAMEDO is used for

TRAMEDO contains the active ingredient, tramadol hydrochloride. Tramadol belongs to a group of medicines called analgesics, also known as "pain relievers" or "pain killers". It is used to relieve moderate to severe pain.

Your doctor, however, may have prescribed TRAMEDO for another purpose. Ask your doctor if you have any questions about why TRAMEDO has been prescribed for you.

TRAMEDO is available only with a doctor's prescription.

Before you take TRAMEDO

When you must not take it

Do not take TRAMEDO if you:

- are allergic to tramadol hydrochloride or any ingredients listed at the end of this leaflet**
- have been drinking alcohol or taking other medicines such as hypnotics** (used to relieve sleeplessness; for example, nitrazepam), **analgesics** (used to relieve pain) **opioids** (used to relieve moderate to severe pain; for example, morphine and codeine) **or psychotropic drugs** (for example chlorpromazine; used to treat schizophrenia and severe anxiety).
- have taken Monoamine Oxidase Inhibitors (MAOIs), a type of medicine used for depression within the last 14 days.** Ask your pharmacist or doctor if you are unsure as to whether or not you are taking a MAOI.
- are known to be sensitive to opioids**
- have uncontrolled epilepsy or epilepsy not adequately controlled by treatment or suffer or ever suffered from fits/seizures/convulsions.**

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

Before you start to take it

You must tell your doctor if you:

- are allergic to any other medicines, foods, preservatives or dyes**
- have or ever had any other health problems, including:**
 - **asthma or any other respiratory (lung) problems**
 - **kidney or liver disease**

- **serious head injury**
- **drug or alcohol dependence (especially opioid dependence)**
- **severe stomach problems**

are pregnant, plan to become pregnant or you are breastfeeding. Your doctor will discuss with you the risks and benefits of taking TRAMEDO if you are pregnant or breastfeeding.

If you have not told your doctor about any of the above, or any other medical condition, tell him/her before you start taking TRAMEDO.

Taking other medicines

Tell your doctor if you are taking any other medicines, or have taken any other medicines in the past two weeks, including any that you buy without a prescription from your pharmacy, supermarket or health shop.

Medicines that can interfere with TRAMEDO include:

- CNS depressants** (for example opioids, anaesthetic agents, phenothiazines, tranquillisers or sedative hypnotics)
- antidepressant drugs known as selective serotonin reuptake inhibitors (SSRI's)** (for example citalopram, fluoxetine and paroxetine), **or tricyclic antidepressants** (for example amitriptyline and despramine)
- coumarin derivatives such as warfarin** (eg. Coumadin, Marevan)
- antipsychotics** (for example chlorpromazine; used to treat schizophrenia and severe anxiety).
- have taken Monoamine Oxidase Inhibitors (MAOIs), a type of medicine used for depression within the last 14 days.** Ask your pharmacist or doctor if you are unsure as to whether or not you are taking a MAOI.
- carbamazepine** (used to treat epilepsy and manic-depressive illness eg. Tegretol, Teril)
- quinidine**
- phenothiazines**
- oral ketoconazole** (used to treat fungal infections)
- oral erythromycin** (used to treat bacterial infections)
- ondansetron** (a medicine used for the prevention and treatment of nausea and vomiting).

These medicines may be affected by TRAMEDO, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking TRAMEDO.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take TRAMEDO

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

How much to take

Take TRAMEDO exactly as your doctor has prescribed.

Your doctor will tell you how many TRAMEDO capsules to take and when to take them each day. Your dose will be based on your condition, age, other medicines you are taking and how you respond to TRAMEDO.

For moderate pain, one TRAMEDO capsule may be sufficient 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 (400mg) 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

Capsules should be swallowed whole with a glass of water.

When to take it

TRAMEDO can be taken with or without food.

How long to take TRAMEDO

Continue taking TRAMEDO until your doctor tells you to stop.

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.

While you are taking TRAMEDO

Things you must do

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

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are currently taking, or have recently taken TRAMEDO.

If you are pregnant, plan to become pregnant or are breastfeeding, tell your doctor or pharmacist.

If you plan to have surgery, 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 prescribed, 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 condition 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.

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 these side effects.

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

- nausea, vomiting, or constipation
- dizziness or drowsiness
- headache
- sweating
- tiredness (fatigue)
- weakness or loss of strength
- dry mouth.

These are the more common side effects of TRAMEDO. Mostly they are mild. Your doctor or pharmacist can help you with these side effects.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre 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 Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea and muscle spasms. Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of TRAMEDO with other medicines, such as SSRIs (refer to *Taking other medicines* section)
- symptoms of "shock" such as rapid, shallow breathing; cold, clammy skin; a rapid, weak pulse; dizziness, weakness and fainting
- difficulty in passing urine or passing no urine
- changes in vision including blurred vision
- heart palpitations, feeling faint or collapsing
- worsening of asthma or breathing problems

fits or seizures (convulsions)
seeing, hearing or feeling things that are not there (hallucinations).

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you should suffer from any of these side effects or any other undesired effect, please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Accident and Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any TRAMEDO by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of TRAMEDO with you if you can.

Keep telephone numbers for these places handy.

After taking TRAMEDO

Storage

Always keep your TRAMEDO capsules in the original blister pack and out of sight and reach of children. Store in a cool dry place where the temperature stays below 30°C and protect from light.

Do not store TRAMEDO, or any other medicine, in the bathroom, on windowsills or in the glove box of the car. Do not refrigerate or freeze your TRAMEDO capsules.

Do not use this medicine after the expiry date shown on either the outer pack or blister pack.

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 the remaining capsules.

Product description

What TRAMEDO capsules look like

TRAMEDO 50 mg capsules are white and orange in colour. Each capsule has "TL 50" printed on the white body and "α" printed on the orange cap.

Ingredients

Each TRAMEDO capsule contains 50 mg of the active ingredient, tramadol. Each capsule also contains the following inactive ingredients:

lactose
microcrystalline cellulose

maize starch
sodium starch glycollate
magnesium stearate
gelatin
titanium dioxide E171
TekPrint SW-9008 Black Ink
colours
- Sunset yellow FCF CI15985
- Quinoline yellow CI47005
- Allura red AC CI16035.

TRAMEDO capsules are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd
PO Box 11183, Ellerslie, Auckland

Telephone: (09) 579 2792

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2 February 2009
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