

TRAMAL[®]

Tramadol hydrochloride immediate release capsules (50 mg) and solution for injection (50 mg/mL, 100 mg/2mL)

WARNING

Limitations of use

TRAMAL[®] 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

TRAMAL[®] 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

TRAMAL[®] 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 TRAMAL[®] 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 TRAMAL[®]

Using TRAMAL[®] 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 TRAMAL[®].

What is in this leaflet

This leaflet answers some common questions about TRAMAL[®]. It does not contain all the available information. It does not replace talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TRAMAL[®] against the benefits this medicine is expected to have 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 TRAMAL[®] is used for

TRAMAL[®] is used to relieve moderate to severe pain and belongs to a group of medicines called analgesics (pain relievers).

Your doctor may have prescribed TRAMAL[®] for another reason. Ask your doctor if you have any questions about why TRAMAL[®] has been prescribed for you.

This medicine is available only with a doctor's prescription.

TRAMAL[®] 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 use TRAMAL[®]

When you must not use this medicine

Do not use TRAMAL[®] if:

- you have an allergy to any of the ingredients (see Product description section below)
- you have an allergy to any other medicines known as opioid analgesics, e.g. morphine or codeine.
- 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" also known as MAOI, or have taken any within the past two weeks. Examples of MAOI-containing medicines are Nardil[®], Parnate[®].
- 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 having treatment for withdrawal from narcotics

Do not take TRAMAL[®] if it is after the expiry date which is printed on the carton box.

Do not use TRAMAL[®] if the packaging is torn or shows signs of tampering.

If it is after the expiry date, or the packaging is damaged, return it to your pharmacist for disposal.

Addiction

You can become addicted to TRAMAL[®] even if you take it exactly as prescribed. TRAMAL[®] 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 TRAMAL[®]. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking TRAMAL[®] suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to TRAMAL[®] may develop, which means that the effect of the medicine may decrease. If this happens, more of the medicine 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.

TRAMAL[®] 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 this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you are known to be sensitive to opioids.
- you have or ever had any other health problems, including:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - fits or convulsions, or take medicines for epilepsy
 - any disorder of the kidney, liver or pancreas
 - any stomach problems
 - severe headaches or feel sick due to a head injury
- you have, or have had, any drug or alcohol dependence
- you have or have had any problems with drug or alcohol dependence.
- If you know you are a CYP2D6 ultra-rapid metaboliser as this will affect how your body breaks down TRAMAL[®], and your dose of TRAMAL[®] may need to be adjusted.
- you have galactose intolerance, or lactase deficiency or glucose-galactose malabsorption.
- you are pregnant or intend to become pregnant. TRAMAL[®] is not recommended for use

during pregnancy. TRAMAL® can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using TRAMAL® during pregnancy.

- you are breastfeeding or plan to breastfeed. TRAMAL® is not recommended for use during breastfeeding. Talk to your doctor about the risks and benefits of using TRAMAL® during pregnancy.
- you are driving or operating machinery. TRAMAL® may make you drowsy or dizzy. Ask your doctor for advice about whether it is safe for you to drive or operate machinery while taking TRAMAL®.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with TRAMAL®. 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.
- 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 TRAMAL®, 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 or pharmacist has more information on medicines to be careful with or avoid while taking TRAMAL®.

How to take TRAMAL®

TRAMAL® is available as capsules (to swallow) and injections (to be given into a vein or muscle). Your doctor will decide:

- how you will receive TRAMAL®,
- what dose and
- for how long.

Carefully follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

TRAMAL® INJECTIONS

TRAMAL® Injection may be given to adults, adolescents or children over the age of 12 years.

TRAMAL® Injection should only be given to children over the age of 12 years under supervision of your doctor.

If you or your child has been prescribed TRAMAL® injections, your doctor or nurse will administer them for you. Take them with you when you visit your doctor. TRAMAL® injections can be injected into a vein or a muscle.

TRAMAL® CAPSULES

How much to take

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

For moderate to severe pain, two TRAMAL® capsules are usually required for the first dose, followed by one or two capsules every four to six hours as required.

If you are over 75 years of age, you may require a lower daily dose or a longer time period between doses of TRAMAL® compared to younger adults.

Do not take more than eight TRAMAL® capsules per day.

Follow carefully all directions given to you by your doctor and pharmacist. These directions may differ from the information in this leaflet.

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

How to take it

TRAMAL® capsules should be swallowed whole, with water.

When to take it

You can take TRAMAL® before, with, or after food.

How long to take it

Depending on the medical condition for which you require TRAMAL®, your doctor may tell you to take it for only a day or two or longer, up to a few months or more.

If you forget to take it

If you forget to take a dose, you can take it as soon as you remember. The next dose should 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 that 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.

While you are using TRAMAL®

Things to be careful of

- Take only as your doctor has told you.
- If you feel that you do not need as much TRAMAL® as your doctor has prescribed for you, talk to your doctor.
- Tell your doctor if your pain is not helped or gets worse. Do not take increased amounts or extra doses of TRAMAL® unless your doctor advises you to.
- Do not give your medicine to anyone else, even if they have similar symptoms to you. Your medicine is for your use only, it may harm other people.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking this medicine.
- 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 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.
- Keep all of your doctor's appointments so that your progress can be checked.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- 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.

In case of overdose

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 one (111) 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 TRAMAL® 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

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 you or someone else may have used too much TRAMAL[®], you should immediately:

- phone the Poisons Information Centre (by calling **0800 POISON (0800 764 766)**), 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.

Side effects

All medicines can cause unwanted effects, and some side-effects have been reported with TRAMAL[®]. Side-effects reported with TRAMAL[®] are usually minor and temporary, but some may be serious.

Do not be alarmed by the following lists of 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 of 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 and high body temperature. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.
- low blood sugar (hypoglycaemia)

This is not a complete listing. Occasionally, other side-effects may be experienced.

Tell your doctor immediately if you experience any of 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 TRAMAL®:

- Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops.
- 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.
- Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.
- TRAMAL® 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 excess.
- 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).

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

Can TRAMAL[®] be addictive?

Prolonged administration of TRAMAL[®] may lead to addiction.

If you are taking TRAMAL[®] for a prolonged period of time, your body may become used to the medicine and mild withdrawal symptoms may occur if you suddenly stop taking the medicine.

It is important therefore to take TRAMAL[®] only as directed by your doctor.

After using TRAMAL[®]

Storage

- **Keep medicines where children cannot reach them.** A locked cupboard at least 1½ metres above the ground is a good place to store medicines.
- Store in a cool, dry place, below 30°C.
- Keep away from direct sunlight.
- Do not use TRAMAL[®] after the use-by-date printed on the label of the pack.

Disposal

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

TRAMAL[®] description

What it looks like

TRAMAL[®] is available as capsules or injections.

Capsules: Each capsule is yellow in colour. They are available in packs of 10, 20, 30 or 50 capsules.

Injections: Clear liquid contained in 1 mL or 2 mL glass ampoules. Available in packs of 5 ampoules.

Ingredients

Active ingredient:

TRAMAL[®] capsules: contain 50 mg tramadol hydrochloride per capsule.

TRAMAL[®] injections: contain tramadol hydrochloride either:

- 50 mg in 1 mL ampoules or
- 100 mg in 2 mL ampoules

Inactive ingredients:

TRAMAL[®] capsules:

- cellulose-microcrystalline
- magnesium stearate
- sodium starch glycollate
- silica-colloidal anhydrous
- iron oxide yellow (CI 77492)
- titanium dioxide
- gelatin
- sodium lauryl sulfate

TRAMAL® injections:

- sodium acetate
- water for injections.

TRAMAL® capsules and injections do not contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor Details

TRAMAL® is supplied in New Zealand by:

Seqirus (NZ) Ltd
P O Box 62590
Greenlane, Auckland 1546
NEW ZEALAND

Telephone: 0800 502 757

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