

New Zealand Consumer Medicine Information

TRAMAL[®]

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

What is in this leaflet

Please read this leaflet carefully before you start using TRAMAL[®].

This leaflet answers some common questions about TRAMAL[®]. It does not contain all the available information. 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 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 with the medicine. 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.

Before you use TRAMAL[®]

When you must not use it

Do not use TRAMAL[®] if:

- **you have a known allergy to TRAMAL[®] or other opioids or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing and swelling of the face (including lips, tongue, throat etc)
- **you are taking medicine for depression containing a "monoamine oxidase inhibitor" (such as Nardil[®], Parnate[®]), or have taken one within the past two weeks.**
- **you are suffering from uncontrolled epilepsy/convulsions or epilepsy not controlled by treatment**

- you drink large amounts of alcohol regularly, are dependent/addicted to other drugs or are undergoing treatment for drug or alcohol withdrawal

Do not give TRAMAL[®] to children under 12 years.

Do not give TRAMAL[®] to children under 18 years following tonsil and/or adenoid surgery.

Do not use TRAMAL[®] after the expiry date printed on the pack. If you take this medicine after the expiry date has passed, it may not work as well.

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

If you are not sure whether you should start using TRAMAL[®], talk to your doctor.

Before you start to use it

You must tell your doctor if:

- you have a known allergy to TRAMAL[®] or any of the ingredients listed at the end of this leaflet.
- you are known to be sensitive to opioids.
- you drink alcohol every day.
- you have or ever had any other health problems, including:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - any diseases of the kidney, liver or pancreas
 - severe stomach problems
 - a serious head injury
 - any fits or convulsions/ epilepsy.
- 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 are pregnant or intend to become pregnant. TRAMAL[®] is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using TRAMAL[®] during pregnancy.
- you are breast-feeding or plan to breast-feed. TRAMAL[®] is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using TRAMAL[®] when breast-feeding.

If you have not told your doctor about any of the above, tell them before you use TRAMAL[®].

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. You should also tell any health professional who is prescribing a new medication for you that you are taking TRAMAL[®].

Some medicines may interfere with TRAMAL[®]. These include:

- carbamazepine (eg. Tegretol[®])
- coumarin derivatives (eg. 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 eg. citalopram – brand names Cipramil[®] or Celapram[®]), serotonin-noradrenaline reuptake inhibitors (SNRI's eg. duloxetine - brand name Cymbalta[®]), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- some antibiotics.

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 TRAMAL[®] is used

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.

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.

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

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.

While you are using TRAMAL[®]

Things you must do

If you become pregnant while you are taking TRAMAL[®], tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking TRAMAL[®].

If your pain is not severe and you feel that you do not need as much TRAMAL[®] as your doctor ordered, consult your doctor.

Tell your doctor if your pain gets worse. Do not take extra doses without checking with your doctor.

If you have to have any tests tell your doctor you are taking TRAMAL[®]. TRAMAL[®] may affect the results of some tests.

Things you must not do

Do not give TRAMAL[®] to anyone else, even if they have the same condition as you.

Do not use TRAMAL[®] to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how TRAMAL[®] affects you. TRAMAL[®] may make you drowsy or dizzy.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the **National Poisons Centre - 0800 POISON (0800 764 766)** or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much TRAMAL[®]. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many capsules, this may result in breathing difficulty and fits or convulsions.

Side effects

Check with your doctor as soon as possible if you have any problems while taking TRAMAL[®], even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, TRAMAL[®] can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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 and 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 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®:

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

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

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, and do not suddenly stop taking it. Your dosage may need to be gradually reduced.

After using TRAMAL®

Storage

Keep your TRAMAL® in the pack until it is time to take them. If you take TRAMAL® out of the pack it may not keep well.

Keep it in a cool dry place where the temperature stays below 30°C. Do not store it in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking TRAMAL® or it passes its expiry date, ask your pharmacist what to do with any TRAMAL® that is left over.

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 1mL or 2mL 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
- gelatine
- 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

TRAMAL[®] is made in Germany by Grunenthal GmbH.

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