

## Consumer Medicine Information

### WARNING

#### Limitations of use

TRAMAL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>

**Using TRAMAL<sup>®</sup> 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<sup>®</sup>.

### What is in this leaflet?

This leaflet answers some common questions about TRAMAL<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> is used for

TRAMAL<sup>®</sup> is used to relieve severe pain and belongs to a group of medicines called opioid analgesics (pain relievers).

Your doctor may have prescribed TRAMAL<sup>®</sup> for another reason. Ask your doctor why TRAMAL<sup>®</sup> has been prescribed for you.

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

**TRAMAL<sup>®</sup> 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<sup>®</sup>

#### *When you must not use it*

**Do not use TRAMAL<sup>®</sup> if:**

- you have a known allergy to TRAMAL<sup>®</sup> 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 have an allergy to any other medicines known as opioid analgesics, eg. 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 a MAOI, or have taken one within the past two weeks. Examples of MAOI-containing medicines are Nardil<sup>®</sup>, Parnate<sup>®</sup>
- 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.

**Do not use TRAMAL<sup>®</sup> 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<sup>®</sup> if the packaging is torn or shows signs of tampering.**

**Addiction**

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

**Tolerance**

Tolerance to TRAMAL<sup>®</sup> 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.

TRAMAL<sup>®</sup> 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 TRAMAL<sup>®</sup>, talk to your doctor.**

***Before you use it***

**You must tell your doctor if:**

- you have a known allergy to TRAMAL<sup>®</sup> 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 ever had any other health problems, including:
  - any lung or breathing problems
  - sleep-related breathing disorders
  - any conditions 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 intend to become pregnant. TRAMAL<sup>®</sup> is not recommended for use during pregnancy. TRAMAL<sup>®</sup> can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using TRAMAL<sup>®</sup> during pregnancy
- you are breast-feeding or plan to breast-feed. TRAMAL<sup>®</sup> is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using TRAMAL<sup>®</sup> when breast-feeding

**If you have not told your doctor about any of the above, tell them before you use TRAMAL<sup>®</sup>.**

### ***Taking other medicines***

**Tell your doctor or pharmacist 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<sup>®</sup>. These include:

- carbamazepine (eg. Tegretol<sup>®</sup>)
- coumarin derivatives (eg. warfarin: Some brand names are Coumadin<sup>®</sup>, or Marevan<sup>®</sup>)
- 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 TRAMAL<sup>®</sup>, 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<sup>®</sup>.

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### **How TRAMAL<sup>®</sup> is used**

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TRAMAL<sup>®</sup> 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<sup>®</sup>;
- what dose; and
- for how long.

### **TRAMAL<sup>®</sup> Injections**

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

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## **How much to take**

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### **TRAMAL<sup>®</sup> Capsules**

An initial dose of, one TRAMAL<sup>®</sup> capsule may provide sufficient pain relief, followed by one or two capsules two or three times a day as required.

For more severe pain, two TRAMAL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> capsules should be swallowed whole, with water.

### ***When to take it***

You can take TRAMAL<sup>®</sup> before, with, or after food.

### ***How long to take it***

This differs between individuals depending on how severe your pain is, how you respond to TRAMAL<sup>®</sup> and the cause of your pain. Ask your doctor for advice on how long you need to take TRAMAL<sup>®</sup>.

**Carefully follow all directions given to you by**

## **your doctor and the pharmacist.**

### ***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.**

### ***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 TRAMAL<sup>®</sup> 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 TRAMAL<sup>®</sup>, 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.

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## **While you are using TRAMAL<sup>®</sup>**

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### ***Things you must do***

If you become pregnant while you are taking TRAMAL<sup>®</sup>, 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<sup>®</sup>.

If your pain is not as severe and you feel that you do not need as much TRAMAL<sup>®</sup> 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 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 TRAMAL<sup>®</sup> to anyone else, even if they have the same condition as you.

Do not use TRAMAL<sup>®</sup> to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they seem to have the same condition as you.

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.

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## **Side effects**

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

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

**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.

**The most common side effects of TRAMAL<sup>®</sup> are:**

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

**The following side effects are less common:**

- 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.

- low blood glucose (hypoglycaemia)

**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<sup>®</sup>:

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.**

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## After using TRAMAL<sup>®</sup>

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### Storage

**Keep your TRAMAL<sup>®</sup> in the pack until it is time to take them.**

If you take TRAMAL<sup>®</sup> 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 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.

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## TRAMAL<sup>®</sup> description

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### What it looks like

TRAMAL<sup>®</sup> 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
- gelatin
- Sodium lauryl sulphate

#### **TRAMAL® injections:**

- sodium acetate
- water for injections.

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

## ***Manufacturer/Sponsor***

TRAMAL® is made in Germany and sponsored in Australia by:

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### **The Australian registration numbers are:**

#### **Injections 50mg/mL:**

AUST R 64009

#### **Injections 100mg/2mL:**

AUST R 64010

#### **Capsules 50mg:**

AUST R 64011

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