

# TRAMAL<sup>®</sup> SR

Tramadol hydrochloride

Sustained Release Tablets

## Consumer Medicine Information

### WARNING

#### Limitations of use

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

Using TRAMAL<sup>®</sup> SR 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> SR.

### What is in this leaflet?

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

TRAMAL<sup>®</sup> SR is used to relieve severe pain which requires daily, long term treatment. It belongs to a group of medicines called opioid analgesics (pain relievers).

TRAMAL<sup>®</sup> SR tablets are designed to release active medicine gradually over several hours.

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

TRAMAL<sup>®</sup> SR is available only on a doctor's prescription.

**TRAMAL<sup>®</sup> SR 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> SR

#### ***When you must not use this medicine***

#### **Do not take TRAMAL<sup>®</sup> SR if:**

- you have an allergy to any of the ingredients listed at the end of this leaflet
- 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 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.

**Do not take TRAMAL® SR if the packaging is torn or shows signs of tampering.**

**Do not take TRAMAL® SR if any tablets look damaged or discoloured.**

**Do not take TRAMAL® SR after the expiry date which is printed on the carton box.**

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® SR even if you take it exactly as prescribed. TRAMAL® SR 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® SR. Taking it may result in physical dependence. Physical dependence means that you may

experience withdrawal symptoms if you stop taking TRAMAL® SR suddenly, so it is important to take it exactly as directed by your doctor.

### **Tolerance**

Tolerance to TRAMAL® SR 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® SR 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 know you are sensitive to opioids
- you drink alcohol
- you have any health problems including:
  - any lung or breathing problems
  - sleep-related breathing disorders
  - fits or convulsions, or take medicines for epilepsy
  - 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
- you have, or have had, any drug or alcohol dependence problems
- you have galactose intolerance, or lactase deficiency or glucose-galactose malabsorption
- you are pregnant or intend to become pregnant. TRAMAL® SR 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® SR during pregnancy
- you are breast feeding or plan to breast feed. TRAMAL® SR is not recommended for use during breast feeding. Talk to your doctor about the risks and benefits of using TRAMAL® SR during pregnancy

**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 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® SR.

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), serotonin-noradrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- some antibiotics.

These medicines may be affected by TRAMAL® SR, 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® SR.

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## How to take TRAMAL® SR

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**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® SR tablets should be swallowed whole with water.

They may be taken, before, with, or after food.

TRAMAL® SR tablets are only designed to work properly if swallowed whole. The tablets may release all their contents at once if broken, chewed, crushed or dissolved, which can be dangerous and cause serious problems, such as an overdose which may be fatal. Unless stated otherwise, they should be swallowed whole.

### **How much to take**

The recommended dosage of TRAMAL® SR is either:

- two TRAMAL® SR 50 tablets twice a day (morning and evening)

OR

- one or two TRAMAL® SR 100 mg tablet(s) twice a day (morning and evening)

OR

- one TRAMAL® SR 150 mg or 200 mg tablet twice a day (morning and evening).

As all patients respond to treatment differently, your doctor may start you on a lower dose.

Do not take more than eight of the 50 mg tablets per day.

Do not take more than four of the 100 mg tablets per day

Do not take more than two of the 150 mg or of the 200 mg tablets per day.

If you are over 75 years of age, you may require a lower daily dose of TRAMAL® SR compared to younger adults.

### **If you forget to take it**

If you forget to take one dose, take the dose when you remember. The following dose should be taken after twelve 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.**

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

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

### **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® SR 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 used too much TRAMAL® SR, 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 taking TRAMAL® SR**

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

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If your pain is not as severe and you feel that you do not need to take as many Tramal® SR tablets 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 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.

### ***Things you must not do***

Do not take this medicine 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 of TRAMAL® SR**

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All medicines can cause unwanted effects, and some side-effects have been reported with TRAMAL® SR. Most side-effects reported with TRAMAL® SR are 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® SR are:**

- dizziness
- sedation, fatigue
- headache
- constipation
- nausea, 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 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, spontaneous muscle contraction, tremor, 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)

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®:

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> SR

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### 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.**

### 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.

Do not use this medicine after the expiry date.

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## Product description

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### What it looks like

TRAMAL<sup>®</sup> SR tablets are sealed in a blister foil pack.

## Ingredients

The active medicine in TRAMAL<sup>®</sup> SR is called tramadol hydrochloride. It is specially made up into tablets that allow the body to absorb the tramadol over a long period, so that dosing need be only twice a day.

TRAMAL<sup>®</sup> SR is available as four distinct strengths of tablet. Each strength of tablet contains a different amount of the active ingredient, tramadol hydrochloride.

#### TRAMAL<sup>®</sup> SR Tablet 50mg

Pale yellow, round. One side imprinted with GRUNENTHAL logo. Other side engraved with "T0". Available in packs of 20 or 60 tablets.

#### TRAMAL<sup>®</sup> SR Tablet 100 mg

White, round. One side imprinted with GRUNENTHAL logo. Other side engraved with "T1" Available in packs of 20 or 60 tablets.

#### TRAMAL<sup>®</sup> SR Tablet 150 mg

Pale orange. One side imprinted with GRUNENTHAL logo. Other side engraved with "T2" Available in packs of 20 or 60 tablets.

#### TRAMAL<sup>®</sup> SR Tablet 200 mg

Deep orange to brown. One side imprinted with GRUNENTHAL logo. Other side engraved with "T3". Available in packs of 20 or 60 tablets

TRAMAL<sup>®</sup> SR tablets also contain the **inactive ingredients**:

- hypromellose
- silica-colloidal anhydrous
- microcrystalline cellulose
- magnesium stearate
- lactose monohydrate
- macrogol 6000
- propylene glycol
- purified talc
- titanium dioxide
- quinoline yellow aluminium lake CI47005 (150 and 200 mg tablets)

- iron oxide red CI77491 (150 and 200 mg tablets)
- iron oxide yellow CI77492 (50 mg and 200 mg tablets only)
- iron oxide black CI77499 (200 mg tablets).

## Sponsor

TRAMAL<sup>®</sup> SR is made by Grünenthal GmbH in Germany and sponsored in Australia by:

Seqirus Pty Ltd  
ABN: 26 160 735 035  
63 Poplar Road  
Parkville VIC 3052  
Australia

Telephone: 1800 642 865

[www.seqirus.com.au](http://www.seqirus.com.au)

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August 2000

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AUST R 121845: Tablets 50 mg  
AUST R 75947: Tablets 100mg  
AUST R 75948: Tablets 150mg  
AUST R 75949: Tablets 200mg

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