

TRAMAL[®] SR sustained release tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I taking TRAMAL[®] SR?

TRAMAL[®] SR contains the active ingredient tramadol hydrochloride. TRAMAL[®] SR is used to relieve severe pain which requires daily, long-term treatment.

For more information, see Section [1. Why am I using TRAMAL[®] SR?](#) in the full CMI.

2. What should I know before I take TRAMAL[®] SR?

Do not take if you have ever had an allergic reaction to TRAMAL[®] SR, other opioids or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use TRAMAL[®] SR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRAMAL[®] SR and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TRAMAL[®] SR?

- Your doctor will tell you the strength and number of TRAMAL[®] SR tablets to take. Follow the instructions given by your doctor carefully.
- TRAMAL[®] SR tablets must be swallowed whole with water.

More instructions can be found in Section [4. How do I use TRAMAL[®] SR?](#) in the full CMI.

5. What should I know while take TRAMAL[®] SR?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using TRAMAL[®] SR.If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.If you become pregnant while taking this medicine, tell your doctor immediately.Tell your doctor if your pain is not helped or gets worse.If you are about to have any blood tests, tell your doctor that you are taking TRAMAL[®] SR.Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">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 using this medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Avoid driving or operating machinery until you know how this medicine affects you. TRAMAL[®] SR 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.
Drinking alcohol	<ul style="list-style-type: none">Do not drink alcohol while you are using this medicine.
Looking after your medicine	<ul style="list-style-type: none">Store in a cool, dry place, below 30°C. Keep TRAMAL[®] SR tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using TRAMAL[®] SR?](#) in the full CMI.

6. Are there any side effects?

TRAMAL[®] SR may cause constipation, nausea, vomiting, indigestion, changes in appetite, hiccups, dry mouth, dizziness, headache, fatigue and sweating.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice: loss of consciousness, breathing changes (slow or shallow breathing), or signs of allergic reaction (skin rash (red spots or patches), itching, shortness of breath, swelling of the face, lips, mouth, tongue or throat). TRAMAL[®] SR poses risk of abuse, misuse and addiction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING

Limitations of use

TRAMAL® 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® 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® 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® 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® SR

Using TRAMAL® 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® SR.

TRAMAL® SR sustained release tablets

Active ingredient: *tramadol hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRAMAL® SR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TRAMAL® SR.**

Where to find information in this leaflet:

- [1. Why am I taking TRAMAL® SR?](#)
- [2. What should I know before I take TRAMAL® SR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take TRAMAL® SR?](#)
- [5. What should I know while taking TRAMAL® SR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking TRAMAL® SR?

TRAMAL® SR contains the active ingredient **tramadol hydrochloride**. Tramadol hydrochloride belongs to a group of medicines called opioid analgesics.

TRAMAL® SR is used to relieve severe pain which requires daily, long term treatment. TRAMAL® SR tablets are designed to release the active ingredient gradually over several hours.

TRAMAL® 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 years.

TRAMAL® SR is available only with a doctor's prescription.

2. What should I know before I use TRAMAL® SR?

Warnings

Do not use TRAMAL® SR if:

- you are allergic to tramadol hydrochloride or any of the ingredients listed at the [end of this leaflet](#). Always check the ingredients to make sure you can take this medicine.
- you have an allergy or sensitivity 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 or 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 AURORIX® (moclobemide), PARNATE® (tranylcypromine).
- you have uncontrolled epilepsy or if your epilepsy is not well-controlled by treatment.
- you are younger than 12 years old or you are between 12 – 18 years of age and are recovering from an operation to remove tonsils and/or adenoids.

Check with your doctor if you:

- you know you are sensitive to opioids
- you drink alcohol
- 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.
- take any medications for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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.

If you are not sure whether you should start taking TRAMAL® SR, talk to your doctor.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

You should not take TRAMAL® SR during pregnancy unless your doctor has told you to. Taking TRAMAL® SR during pregnancy may lead to withdrawal symptoms in the newborn baby.

You should not take TRAMAL® SR during labour as it can cause breathing problems or signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed. TRAMAL® SR is not recommended for use during breastfeeding.

Children

TRAMAL® SR is for use in adults and children over 12 years of age.

Do not give this medicine to children younger than 12 years old or people who are between 12 – 18 years of age and are recovering from an operation to remove tonsils and/or adenoids.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TRAMAL® SR and affect how it works. 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 or psychiatric conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-noradrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, quinidine, phenothiazines or antipsychotics
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRAMAL® SR.

4. How do I take TRAMAL® SR?

How much to take

The recommended dosage of TRAMAL® SR is either:

- two TRAMAL® SR 50 mg 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).

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.

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

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

Follow the instructions provided by your doctor and use TRAMAL® SR until your doctor tells you to stop. If you do not understand the instructions provided to you, ask your doctor or pharmacist for help.

How to take TRAMAL® SR

TRAMAL® SR tablets must be swallowed whole with water. They may be taken before, with, or after food.

Swallow the tablets whole with a glass of water. They must NOT be chewed, crushed, broken or dissolved. This will release all the analgesic quite quickly. Side-effects may then occur.

How to long to take TRAMAL® SR

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 forget to use TRAMAL® SR

TRAMAL® SR should be used regularly at the same time each day.

If you miss your dose at the usual time, you can take it as soon as you remember it. The next dose should be taken after 12 hours, or as prescribed by your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much TRAMAL® SR

If you or someone else receive too much (overdose), and experiences 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
- Serotonin syndrome symptoms, sweating, agitation, muscle twitching, tremor, spontaneous muscle contraction, high body temperature.

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 that you or someone else may have used too much TRAMAL® SR, you may need urgent medical attention.

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.

5. What should I know while using TRAMAL® SR?

Things you should do

- If you are about to start 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.

Call your doctor straight away if you:

Do not feel well while taking TRAMAL® SR.

Things you should not do

- Do not stop taking your medicine or change the dosage without checking with your doctor. Some people may feel unwell if they suddenly stop taking TRAMAL® SR. If you suddenly stop taking TRAMAL® SR you may experience withdrawal symptoms (see 'Withdrawal' section above).
- Do not give your medicine to anyone else, even if they seem to have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

Avoid driving, operating heavy machinery or using any machines or tools until you know how TRAMAL® SR affects you.

TRAMAL® SR 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are taking TRAMAL® SR.

Drinking alcohol while taking TRAMAL® SR may cause serious side effects such as drowsiness, breathing difficulties, and loss of consciousness.

Looking after your medicine

- Keep your TRAMAL® SR tablets in the pack until it is time to take them.
- Keep TRAMAL® SR in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If the medicine is damaged or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering, or the tablets do not quite look right.

Do not take this medicine after the expiry date.

Getting rid of any unwanted medicine

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of the time they are not serious, however, sometimes they are serious and may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal and mouth related: Mild abdominal problems such as constipation, nausea, vomiting, indigestion, changes in appetite, hiccups or dry mouth.</p> <p>Neurological related:</p> <ul style="list-style-type: none"> • dizziness • headache <p>General body related:</p> <ul style="list-style-type: none"> • fatigue • sweating • skin reactions <p>Sleep-related breathing disorders:</p> <ul style="list-style-type: none"> • 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 excessive drowsiness during the day. <p>Sleep-related:</p> <ul style="list-style-type: none"> • Sleep disturbance 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction related:</p> <ul style="list-style-type: none"> • skin rash (red spots or patches), itching, hives, skin lumps • swelling or puffiness of the eyelids, face or lips <p>Heart or lung related:</p> <ul style="list-style-type: none"> • respiratory depression (slow or shallow breathing) • sudden onset of low blood pressure, collapse • chest tightness, wheezing or pain in the chest • heart palpitations, faintness or collapse • low blood glucose (hypoglycaemia) <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> • sedation • tremor, seizures • convulsions • 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 hydrochloride with other medicines which increase serotonin effects, for example, the selective serotonin reuptake inhibitors (SSRI's) and antidepressants. • hallucinations • confusion • improvement in mood <p>Muscle-related:</p> <ul style="list-style-type: none"> • muscle weakness <p>Urinary related:</p> <ul style="list-style-type: none"> • difficulty in passing urine <p>Eye related:</p> <ul style="list-style-type: none"> • blurred vision <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects (continued)	What to do
<p>Gastrointestinal related (continued):</p> <ul style="list-style-type: none"> • Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time. <p>Hormone related:</p> <ul style="list-style-type: none"> • Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops. • 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What TRAMAL® SR contains

Active ingredient (main ingredient)	tramadol hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• hypromellose• silica-colloidal anhydrous• microcrystalline cellulose• magnesium stearate• lactose monohydrate• macrogol 6000• propylene glycol• purified talc• titanium dioxide• quinoline yellow• aluminium lake CI47005 (150 mg and 200 mg tablets only)• iron oxide red CI77491 (150 mg and 200 mg tablets only)• iron oxide yellow CI77492 (50 mg and 200 mg tablets only)• iron oxide black CI77499 (200 mg tablets only)
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What TRAMAL® SR looks like

TRAMAL® SR tablets are sealed in a blister foil pack.

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

TRAMAL® SR Tablet 50 mg (AUST R 121845)

Pale yellow coloured, round, biconvex film-coated tablets, engraved with "T0" on one side and the Grünenthal logo on the other side.

TRAMAL® SR Tablet 100 mg (AUST R 75947)

White, round, biconvex film-coated tablets, engraved with "T1" on one side and the Grünenthal logo on the other side.

TRAMAL® SR Tablet 150 mg (AUST R 75948)

Pale orange coloured, round, biconvex film-coated tablets, engraved with "T2" on one side and the Grünenthal logo on the other side.

TRAMAL® SR Tablet 200 mg (AUST R 75949)

Slightly brownish orange coloured, round biconvex film coated tablets, engraved with "T3" on one side and the Grünenthal logo on the other side.

The registered pack sizes for TRAMAL® SR are 4 tablets (sample pack), 20 tablet pack and 60 tablet pack. All strengths and pack sizes may not be available.

Who distributes TRAMAL® SR

TRAMAL® SR is manufactured by Grünenthal GmbH in Germany and sponsored in Australia by:

Seqirus Pty Ltd
ABN: 26 160 735 035
655 Elizabeth Street
Melbourne VIC 3000 Australia

Telephone: 1800 642 865
www.cslseqirus.com.au

Distributor:
Seqirus (Australia) Pty Ltd
Melbourne, Victoria
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