TRAMEDO® SR

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 TRAMEDO SR?

TRAMEDO SR contains the active ingredient tramadol hydrochloride. TRAMEDO SR is used to relieve severe pain. For more information, see Section 1. Why am I taking TRAMEDO SR? in the full CMI.

2. What should I know before I take TRAMEDO SR?

Do not take if you have ever had an allergic reaction to tramadol hydrochloride, 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 take TRAMEDO SR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRAMEDO 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 TRAMEDO SR?

- Swallow the tablets whole with a glass of water.
- Discuss with your doctor the correct dose for you. Do not take more than four of the 100 mg tablets per day or two of the 150 mg or of the 200 mg tablets per day.

More instructions can be found in Section 4. How do I take TRAMEDO SR? in the full CMI.

5. What should I know while taking TRAMEDO SR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking TRAMEDO SR. • Remind your doctor if you are allergic to tramadol, opioids or any of the ingredients in this medicine or if you have had any problems with drug or alcohol dependence. • If you become pregnant or plan to breast-feed while taking TRAMEDO SR, tell your doctor immediately. • If you are about started any new medicine, tell your doctor or pharmacist that you are taking TRAMEDO SR. • If your pain is not as severe or if your pain is not helped or gets worse, talk to your doctor. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. • If you have to have any blood tests tell your doctor you are taking this medicine.
Things you should not do	• Do not stop taking this medicine or change the dosage without discussing this with your doctor. • Do not give this medicine to anyone else, or use it to treat any other complaints.
Driving or using machines	• Be careful when driving or operating machinery until you know how this medicine affects you.
Drinking alcohol	• Drinking alcohol while taking this medicine can cause drowsiness, coma or death. • Do not drink alcohol while using this medicine.
Looking after your medicine	• Keep your tablets in the pack until it is time to take them. • Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while taking TRAMEDO SR? in the full CMI.

6. Are there any side effects?

Common side effects are dizziness, sedation, fatigue, headache, constipation, nausea or vomiting, sweating or dry mouth, cramps, sleep apnoea. Serious side effects are 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 or convulsions, coma, stupor, personality changes. Tell your doctor if you have extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure.

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

TRAMEDO 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

TRAMEDO 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

TRAMEDO 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 TRAMEDO 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 TRAMEDO SR

Using TRAMEDO 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 TRAMEDO SR.

TRAMEDO SR®

Active ingredient(s): *tramadol hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRAMEDO 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 using TRAMEDO SR.**

Where to find information in this leaflet:

1. Why am I taking TRAMEDO SR?
2. What should I know before I take TRAMEDO SR?
3. What if I am taking other medicines?
4. How do I take TRAMEDO SR?
5. What should I know while taking TRAMEDO SR?
6. Are there any side effects?
7. Product details

1. Why am I taking TRAMEDO SR?

TRAMEDO SR contains the active ingredient tramadol hydrochloride.

TRAMEDO SR is used to relieve severe pain over a long period of time. It belongs to a group of medicines called opioid analgesics (pain relievers). TRAMEDO SR tablets are designed to release active medicine gradually over several hours.

TRAMEDO SR is for use in adults and children over 12 years of age and should not be used in children under 12 years of age or following the removal of tonsils and/or adenoids in people under 18.

2. What should I know before I use TRAMEDO SR?

Warnings

Do not take TRAMEDO SR if:

- you are allergic to tramadol hydrochloride, any other opioid analgesics (e.g. morphine or codeine), 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). Always check the ingredients to make sure you can take this medicine.
- 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®, Parnate®
- 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 use TRAMEDO SR after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Addiction

You can become addicted to TRAMEDO SR even if you take it exactly as prescribed.

TRAMEDO 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 TRAMEDO SR. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking TRAMEDO SR suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to TRAMEDO 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 TRAMEDO SR, talk to your doctor.

Pregnancy and breastfeeding

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

TRAMEDO SR given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 TRAMEDO SR and affect how it works. These include:

- carbamazepine (eg. Tegretol®)
- coumarin derivatives (eg.warfarin: Some brand names are Coumadin®, or Marevan®)
- medicine for irregular or rapid heart beat
- some antibiotics
- 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
- 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 TRAMEDO SR.

4. How do I take TRAMEDO SR?

How much to take

The recommended dosage of TRAMEDO SR is either:

- one or two TRAMEDO SR 100 mg tablet(s) twice a day (morning and evening); or
- one TRAMEDO SR 150 mg or 200 mg tablet twice a day (morning and evening).

TRAMEDO SR tablets allow the body to absorb the active ingredient tramadol over a long period, so that dosing need be only twice a day

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

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.

Patients over 75 years may need a reduced daily dose of TRAMEDO SR compared to younger adults.

When and how to take TRAMEDO SR

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

How long to take TRAMEDO SR

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

If you forget to take TRAMEDO SR

If you forget to take a dose, you can take it as soon as you remember. The next 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 it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you take too much TRAMEDO SR

If you or someone else receives 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 TRAMEDO 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.

If you think that you have used too much TRAMEDO 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 TRAMEDO SR?

Things you should do

Tell your doctor before you take TRAMEDO SR if:

- you have a known allergy to TRAMEDO SR 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 affects 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. TRAMEDO SR is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using TRAMEDO SR during pregnancy.
- you are breast-feeding or plan to breast-feed. TRAMEDO SR is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using TRAMEDO SR when breastfeeding.

Things you should not do

- Do not give TRAMEDO SR to anyone else, even if they have the same condition as you.
- Do not use TRAMEDO SR to treat any other complaints unless your doctor tells you to.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRAMEDO SR affects you.

TRAMEDO 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.

Alcohol taken with TRAMEDO SR may cause may result in severe drowsiness, decreased awareness, breathing problems, coma and death.

Things you must do while taking TRAMEDO SR

If you become pregnant while you are taking TRAMEDO SR, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking TRAMEDO SR.

If your pain is not as severe and you feel that you do not need as much TRAMEDO SR 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.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°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.

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 them are minor and temporary. However, some side effects 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
Common: • dizziness • sedation, fatigue • headache • constipation • nausea or vomiting • sweating • dry mouth **Less Common:** • indigestion • hiccups	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• changes in appetite • skin reactions • sudden onset of low blood pressure, collapse • muscle weakness, cramps • tremor • seizures • respiratory depression • improvement in mood • confusion • sleep disturbance, apnoea • 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.	

Serious side effects

Serious side effects	What to do
• 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 • coma, stupor • personality changes	**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.**

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.

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 TRAMEDO SR contains

Active ingredient (main ingredient)	Tramadol hydrochloride
Other ingredients (inactive ingredients)	Calcium hydrogen phosphate dihydrate Hyprolose Colloidal anhydrous silica Magnesium stearate

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

What TRAMEDO SR looks like

TRAMEDO SR 100 mg – off-white, round biconvex tablet (AUST R 154383)

TRAMEDO SR 150 mg – off-white, capsule shaped tablet (AUST R 154388)

TRAMEDO SR 200 mg – off-white, capsule shaped tablet (AUST R 154389)

All tablets are contained in a blister pack within a carton of 20 tablets.

Who distributes TRAMEDO SR

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in August 2025.

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