

# Tramadol Sandoz® 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 using Tramadol Sandoz SR?

Tramadol Sandoz SR contains the active ingredient tramadol hydrochloride. Tramadol Sandoz SR is used to relieve severe pain which requires daily, long term treatment.

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

### 2. What should I know before I use Tramadol Sandoz SR?

Do not use if you have ever had an allergic reaction to tramadol hydrochloride 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 Tramadol Sandoz SR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Tramadol Sandoz 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 use Tramadol Sandoz SR?

- Follow all directions given to you by your doctor or pharmacist carefully.
- Ask your doctor or pharmacist if you are unsure of the correct dose for you.

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

### 5. What should I know while using Tramadol Sandoz SR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Tramadol Sandoz SR.</li><li>• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>• If your pain lessens or gets worse, consult your doctor.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take Tramadol Sandoz SR to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Tramadol Sandoz SR affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• You must not drink alcohol while using Tramadol Sandoz SR.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in the original container. If you take it out of its original container it may not keep well.</li><li>• Keep your medicine in a cool dry place where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

Less serious side effects are dizziness, sedation, fatigue, headache, constipation, nausea or vomiting, sweating, and dry mouth.

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**

Tramadol Sandoz 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**

Tramadol Sandoz SR poses risk of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

**Life threatening respiratory depression**

Tramadol Sandoz 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 Tramadol Sandoz 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 Tramadol Sandoz SR**

**Using Tramadol Sandoz 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 Tramadol Sandoz SR.

# Tramadol Sandoz<sup>®</sup> SR

Active ingredient(s): *tramadol hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Tramadol Sandoz 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 Tramadol Sandoz SR.**

Where to find information in this leaflet:

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

### 1. Why am I using Tramadol Sandoz SR?

Tramadol Sandoz SR contains the active ingredient **tramadol hydrochloride**. Tramadol Sandoz SR belongs to a group of medicines called opioid analgesics (pain relievers).

**Tramadol Sandoz SR is used to relieve severe pain which requires daily, long term treatment.**

Tramadol Sandoz SR tablets are designed to release active medicine gradually over several hours.

**Tramadol Sandoz SR tablets 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.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

## 2. What should I know before I use Tramadol Sandoz SR?

### Warnings

**Do not use Tramadol Sandoz SR if:**

- you are allergic to tramadol hydrochloride, any other similar medicines known as opioid analgesics (e.g. morphine, codeine), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin
- 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 (medicine that affect mood and emotions)
- you are taking medicines for depression containing a "monoamine oxidase inhibitors" also known as MAOI,

or have taken any within the last two weeks (e.g. 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
- it is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering
- any tablets look damaged or discoloured.

## Addiction

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

## Tolerance

Tolerance to Tramadol Sandoz 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 tell 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.

Tramadol Sandoz 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.**

## Check with your doctor if you:

- have any other medical conditions, 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
- take any medicines for any other condition
- know you are sensitive to opioids
- drink alcohol
- have or have had any drug or alcohol dependence problems
- have galactose intolerance, or lactase deficiency or glucose-galactose malabsorption.

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?](#)

## Pregnancy and breastfeeding

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

**Tramadol Sandoz SR is not recommended for use during pregnancy.** Tramadol Sandoz SR can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using Tramadol Sandoz SR during pregnancy.

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

**Tramadol Sandoz SR is not recommended for use during breastfeeding.** Talk to your doctor about the risks and benefits of using Tramadol Sandoz SR during breastfeeding

## 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 Tramadol Sandoz SR. 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 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
- 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.

These medicines may be affected by Tramadol Sandoz SR, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Other interactions not listed above may also occur.

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

## 4. How do I use Tramadol Sandoz SR?

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

### How much to take

- It is recommended that Tramadol Sandoz SR be taken as:  
one to two 100 mg tablet(s) twice a day (morning and evening)  
OR  
one 150 mg or 200 mg tablet twice a day (morning and evening).
- It is specially made up into tablets that allow the body to absorb the tramadol over a long period, so that dosing needs only to be 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 Tramadol Sandoz SR 100 mg tablets or more than two of the Tramadol Sandoz SR 150 mg or of the 200 mg tablets per day.
- Patients over 75 years may need a lower daily dose of Tramadol Sandoz SR compared to younger adults.
- **Ask your doctor or pharmacist if you are unsure of the correct dose for you.**
- They will tell you exactly how much to take.
- **Follow the instructions they give you.**
- If you take the wrong dose, Tramadol Sandoz SR may not work as well and your problem may not improve.

### How to take Tramadol Sandoz SR

- Swallow the tablets whole with a full glass of water.
- **Do not break, chew, crush or dissolve them.**
- Tramadol Sandoz SR are only designed to work properly if swallowed whole. The tablets are designed to release the medicine over a prolonged period. If they are broken, chewed, crushed or dissolved the medicine will be released at once, which can be dangerous and cause serious problems, such as an overdose which may be fatal. Unless stated otherwise, they should be swallowed whole.

### When to take Tramadol Sandoz SR

- **Take your medicine before, during or immediately after a meal, at about the same time each day.**
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### How to long to take Tramadol Sandoz SR

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

### If you forget to use Tramadol Sandoz SR

Tramadol Sandoz SR should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and continue to take it as you would normally. The following dose should be taken after twelve 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 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

### If you use too much Tramadol Sandoz SR

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 Tramadol Sandoz 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

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 Tramadol Sandoz SR, you or they 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 Tramadol Sandoz SR?

### Things you should do

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tramadol Sandoz SR.**

**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.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**Tell your doctor if you feel you do not need as much Tramadol Sandoz SR.**

They may adjust your dose.

**Tell your doctor if you feel Tramadol Sandoz SR is not helping or your pain is worsening.**

Do not take increased amounts or extra doses unless your doctor advises you to.

**Call your doctor straight away if you:**

- Become pregnant while using this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Tramadol Sandoz SR.

### Things you should not do

- **Do not take Tramadol Sandoz SR to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **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 Tramadol Sandoz SR affects you.**

This medicine may cause drowsiness, dizziness or light-headedness in some people, especially after the first dose. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

**You must not drink alcohol while using Tramadol Sandoz SR.**

### Looking after your medicine

- Keep your medicine in the original container. If you take it out of its original container it may not keep well.
- Keep your medicine 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.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### 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
<ul style="list-style-type: none"> <li>• dizziness</li> <li>• sedation, fatigue</li> <li>• headache</li> <li>• constipation</li> <li>• nausea, vomiting</li> <li>• sweating</li> <li>• dry mouth.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>indigestion</li> <li>hiccups</li> <li>changes in appetite</li> <li>skin reactions</li> <li>sudden onset of low blood pressure, collapse</li> <li>muscle weakness</li> <li>tremor</li> <li>seizures</li> <li>respiratory depression</li> <li>improvement of mood</li> <li>confusion</li> <li>sleep disturbance</li> <li>blurred vision</li> <li>difficulty in passing urine</li> <li>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.</li> <li>low blood glucose (hypoglycaemia).</li> </ul>	<p><b>Tell your doctor as soon as possible if you experience any of the following symptoms.</b></p>

## Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> <li>skin rash (red spots or patches), itching hives, skin lumps</li> <li>swelling or puffiness of the eyelids, face or lips</li> <li>chest tightness, wheezing or pain in the chest</li> <li>heart palpitations, faintness or collapse</li> <li>hallucinations</li> <li>convulsions</li> </ul>	<p><b>Stop taking Tramadol Sandoz SR, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

Talk to your doctor if you experience any of the following symptoms while taking Tramadol Sandoz SR:

- Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops.
- 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.

- Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.
- Tramadol Sandoz SR 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.
- 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, 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](http://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 Tramadol Sandoz SR contains

<b>Active ingredient (main ingredient)</b>	tramadol hydrochloride
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate hypromellose povidone magnesium stearate colloidal anhydrous silica hydrogenated castor oil indigo carmine quinoline yellow aluminium hydroxide calcium hydrogen phosphate maize starch microcrystalline cellulose sodium starch glycolate
<b>Potential allergens</b>	sugars as lactose

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

### **What Tramadol Sandoz SR looks like**

Tramadol Sandoz SR comes in 3 strengths:

Tramadol Sandoz SR 100 mg - flat, round bi-layer-tablets with facet, initial layer white, slow-release layer green with one-sided identification mark T R (AUST R 99239).  
100R

Tramadol Sandoz SR 150 mg - flat, round bi-layer-tablets with facet, initial layer white, slow-release layer green with one-sided identification mark T R (AUST R 99252).  
150R

Tramadol Sandoz SR 200 mg - flat, round bi-layer-tablets with facet, initial layer white, slow-release layer green with one-sided identification mark T R (AUST R 99258).  
200R

Available in blisters of 20 sustained-release tablets.

### **Who distributes Tramadol Sandoz SR**

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

This leaflet was prepared in November 2025.

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