

Tramadol Sandoz SR®

tramadol hydrochloride sustained-release tablets

Consumer Medicine Information

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.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Tramadol Sandoz SR.

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 this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT TRAMADOL SANDOZ SR IS USED FOR

The name of your medicine is Tramadol Sandoz SR. This medicine is used to relieve severe pain which requires daily, long term treatment.

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

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

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

Your doctor may have prescribed it for another reason.

Tramadol Sandoz SR is available only on a doctor's prescription.

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.

BEFORE YOU TAKE TRAMADOL SANDOZ SR

When you must not take it

Do not take this medicine if you have an allergy to:

- tramadol hydrochloride, the active ingredient or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines known as opioid analgesics e.g. morphine, codeine.

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.

Do not take this medicine if you have or have had any of the following medical conditions:

- have respiratory disease or slow or shallow breathing
- if 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)
- 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)
- 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.

Tramadol Sandoz 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Do not take Tramadol Sandoz SR if any tablets look damaged or discoloured.

If it has expired or is damaged, return it to your pharmacist for disposal.

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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

You must tell your doctor if:

- you know you are sensitive to opioids
- you drink alcohol
- you have any health problems including:
 - any condition that may affect how your kidney or liver work
 - any stomach problems
 - any lung or breathing problems
 - sleep-related breathing disorders
 - fits or convulsions, or take medicines for epilepsy
 - 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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.

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.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Tramadol Sandoz SR.

Taking other medicines

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

Some medicines and Tramadol Sandoz SR may interfere with each other. These include:

- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-noradrenaline reuptake inhibitors (SNRI's) and tricyclic anti-depressants (TCA's), quinidine, phenothiazines or anti-psychotics
- medicines to help you sleep
- medicine for irregular or rapid heartbeats
- carbamazepine (e.g. Tegretol)
- coumarin derivatives (e.g. warfarin, brand names are Coumadin or Marevan)
- some antibiotics.

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE 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 it

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 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 take it

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 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 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

If you think you or someone else may have used too much Tramadol Sandoz SR, you should immediately:

- phone the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice
- contact your doctor
- go to Accident and Emergency at the nearest hospital

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

WHILE YOU ARE TAKING TRAMADOL SANDOZ SR

Things you must 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.

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

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

They may adjust your dose.

Tell you 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.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery 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.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tramadol Sandoz SR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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 Tramadol Sandoz SR are:

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

The following side-effects are less common:

- confusion
- changes in appetite
- indigestion
- hiccups
- muscle weakness
- tremor
- improvement of mood
- sleep disturbance
- blurred vision

- skin reactions
- difficulty in passing urine
- sudden onset of low blood pressure, collapse
- seizures
- respiratory depression
- 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)

This is not a complete listing.

Occasionally, other side-effects may be experienced.

If any of the following happen, stop taking Tramadol Sandoz SR and tell your doctor immediately 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
- hallucination
- fits or convulsions.

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

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 is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING TRAMADOL SANDOZ SR

Storage

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.

Do not store Tramadol Sandoz SR or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it 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
100 R

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
150 R

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
200 R

Available in blisters of 20 sustained-release tablets.

Ingredients

Active Ingredient:

- Tramadol Sandoz SR 100 mg - 100 mg tramadol hydrochloride
- Tramadol Sandoz SR 150 mg - 150 mg tramadol hydrochloride
- Tramadol Sandoz SR 200 mg - 200 mg tramadol hydrochloride.

Inactive ingredients:

- lactose
- 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 glycollate.

This medicine does not contain sucrose or gluten.

Supplier

Tramadol Sandoz SR is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park
NSW 2113
Australia
Tel: 1800 726 369

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bay
Auckland 0754
New Zealand
Tel: 0800 354 335

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Australian Register Number

100 mg sustained-release tablets:
AUST R 99239 (blisters)

150 mg sustained-release tablets:
AUST R 99252 (blisters)

200 mg sustained-release tablets:
AUST R 99258 (blisters)