

Tramadol Sandoz SR®

tramadol hydrochloride sustained-release tablets

Consumer Medicine Information

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 moderate to severe pain.

It contains the active ingredient tramadol hydrochloride. Tramadol hydrochloride belongs to a group of medicines called analgesics.

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.

This medicine is very unlikely to be addictive if taken as prescribed by your doctor. However, if you take Tramadol Sandoz SR for a long period, your body may become used to the medicine and you may experience some symptoms of withdrawal if you stop taking it suddenly. It is important that you discuss this issue with your doctor.

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:

- regularly drink large quantities of alcohol or if you have taken other substances which can affect your level of consciousness
- taking medicines for depression known as monoamine oxidase inhibitors (MAOI) or have taken any within the last two weeks (e.g. Nardil, Parnate)

- treatment for drug or substance dependence.

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

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

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

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.

Tell your doctor if you have or have had any of the following medical conditions:

- disorder of the kidney, liver or pancreas
- stomach problems
- lung or breathing problems, such as asthma
- fits or convulsions
- head injury or severe headache
- drug, alcohol or substance dependence
- galactose intolerance or lactase deficiency or glucose-galactose malabsorption.

Tell your doctor if you are pregnant or plan to become pregnant or are 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 including selective serotonin reuptake inhibitors (SSRI's) and tricyclic anti-depressants (TCA's)
- medicines for mental or psychiatric disorders including phenothiazines
- medicines to help you sleep
- quinidine, a medicine used to treat irregular heartbeats
- carbamazepine, a medicine to treat epilepsy
- coumarin derivatives (e.g. warfarin, brand names 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.

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 100mg tablet(s) twice a day (morning and evening)

OR

one 150mg or 200mg 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 100mg tablets or more than two of the Tramadol Sandoz SR 150mg or of the 200mg tablets per day.

Patients over 75 years may need a lower daily dose of Tramadol Sandoz SR.

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.

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, increasing the chance of side-effects.

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

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. Your doctor will tell you when and how Tramadol Sandoz SR should be discontinued. This depends on how severe your pain is and how you respond to 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.

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)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Tramadol Sandoz SR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, confusion, breathing difficulty, fits or convulsions.

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 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 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.

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.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness or drowsiness
- headache
- fatigue
- constipation
- nausea or vomiting
- sweating
- dry mouth
- indigestion
- changes in appetite.

These are the more common side effects of the medicine. Mostly, these are mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- confusion
- anxiety
- muscle weakness
- tremor
- change in mood
- sleep disturbance
- blurred vision
- skin reactions including rash, itching hives and skin lumps
- difficulty in passing urine
- sudden onset of low blood pressure.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking Tramadol Sandoz SR and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing
- breathing difficulties including chest tightness, chest pains and wheezing
- faintness or collapse
- fast or irregular heartbeats
- hallucination
- fits or convulsions
- serotonin syndrome: symptoms include fever, sweating, confusion, agitation, diarrhoea, muscle twitching and difficulty with walking and balance.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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 100mg - flat, round bi-layer-tablets with facet, initial layer white, slow-release layer green with one-sided identification mark "TR/100R"

Tramadol Sandoz SR 150mg - flat, round bi-layer-tablets with facet, initial layer white, slow-release layer green with one-sided identification mark "TR/150R"

Tramadol Sandoz SR 200mg - flat, round bi-layer-tablets with facet, initial layer white, slow-release layer green with one-sided identification mark "TR/200R"

Available in blisters of 20 sustained-release tablets.

Ingredients

Active Ingredient:

- Tramadol Sandoz SR 100mg - 100mg tramadol hydrochloride
- Tramadol Sandoz SR 150mg - 150mg tramadol hydrochloride
- Tramadol Sandoz SR 200mg - 200mg 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 634 500

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

This leaflet was revised in Oct 2016.

Australian Register Number

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

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

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