

Tramadol Sandoz®

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?

Tramadol Sandoz contains the active ingredient tramadol hydrochloride. Tramadol Sandoz is used to relieve severe pain. For more information, see Section [1. Why am I using Tramadol Sandoz?](#) in the full CMI.

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

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?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tramadol Sandoz 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?

- Your doctor will decide what dose and how long you will receive Tramadol Sandoz. This depends on your condition and how you react to this medicine.
- Tramadol Sandoz should only be given by a nurse or doctor. It can be given as an injection into your veins or your muscles.

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

5. What should I know while using Tramadol Sandoz?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Tramadol Sandoz.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 using this medicine, tell your doctor immediately.If your pain lessens or gets worse, consult your doctor.If you are about to have any blood tests, tell your doctor that you are taking Tramadol Sandoz. It may affect the results of some tests. |
| Things you should not do | <ul style="list-style-type: none">Do not use Tramadol Sandoz 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 | <ul style="list-style-type: none">Be careful driving or operating machinery until you know how Tramadol Sandoz affects you. |
| Drinking alcohol | <ul style="list-style-type: none">You must not drink alcohol while using Tramadol Sandoz. |
| Looking after your medicine | <ul style="list-style-type: none">Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light. |

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

Using Tramadol Sandoz 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.

Tramadol Sandoz®

Active ingredient(s): *tramadol hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Tramadol Sandoz?

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

Tramadol Sandoz is used to relieve severe pain.

Tramadol Sandoz 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.

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

Warnings

Do not use Tramadol Sandoz 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 throat or other parts of the body
 - skin rash, itching or hives on the skin
- you have respiratory disease or slow or shallow breathing
- you have taken large quantities 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 medicines for depression known as monoamine oxidase inhibitors (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.

Addiction

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

Tolerance

Tolerance to Tramadol Sandoz 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.

Tramadol Sandoz 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 using 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
 - 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
 - any fits or convulsions, or take medicines for epilepsy
- take any medicines for any other condition
- are known to be sensitive to opioids
- drink alcohol
- have or have had any problems with drug or alcohol dependence.

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 is not recommended for use during pregnancy.

Tramadol Sandoz can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using Tramadol Sandoz during pregnancy.

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

Tramadol Sandoz is not recommended for use 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 and Tramadol Sandoz may interfere with each other. These include:

- carbamazepine (eg. Tegretol)
- coumarin derivatives (e.g. warfarin: brand names are Coumadin or Marevan)
- medicines for irregular or rapid heart beats
- medicines for depression, sleeplessness or mental conditions including 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 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.

4. How do I use Tramadol Sandoz?

How much to take

- Your doctor will decide what dose and how long you will receive Tramadol Sandoz. This depends on your condition and how you react to this medicine. Tramadol Sandoz should only be given by a nurse or doctor. It can be given as an injection into your veins or your muscles.

How to take Tramadol Sandoz

- Tramadol Sandoz should only be given by a nurse or doctor. It can be given as an injection into your veins or your muscles.

If you use too much Tramadol Sandoz

As Tramadol Sandoz is given under medical supervision, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given Tramadol Sandoz, tell your doctor or nurse immediately.

Symptoms of an overdose may include drowsiness, dizziness or unconsciousness, confusion, slow, unusual or difficult breathing, slow or weak heartbeat, nausea or vomiting, fits or convulsions.

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 or someone else receive too much (overdose), you should immediately 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 that was prescribed for you.

5. What should I know while using Tramadol Sandoz?

Things you should do

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

Tell any other doctors, dentists and pharmacists who treat you that you are being given 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 your pain is not as severe and you feel that you do not need as much Tramadol Sandoz 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.

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.

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.

Things you should not do

- **Do not use Tramadol Sandoz 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 affects you.

This medicine may cause drowsiness, dizziness or light-headedness 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

You must not drink alcohol while using Tramadol Sandoz.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- Keep your medicine in a cool dry place where the temperature stays below 25°C.
- Protect from light.

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.

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">dizzinesssedation, fatigueheadacheconstipationnausea or vomitingsweatingdry mouth | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">indigestionhiccupschanges in appetiteskin reactionssudden onset of low blood pressure, collapsemuscle weaknesstremorseizuresrespiratory depressionimprovement in moodconfusionsleep disturbanceblurred visiondifficulty in passing urineSerotonin 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 antidepressantslow blood glucose (hypoglycaemia) | Tell your doctor as soon as possible if you experience any of the following symptoms. |

Very serious side effects

| Very serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">skin rash (red spots or patches), itching, hives, skin lumpsswelling or puffiness of the eyelids, face or lipschest tightness, wheezing or pain in the chestheart palpitations, faintness or collapsehallucinationsconvulsions | Stop taking Tramadol Sandoz, 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. |

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

- 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 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. 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 contains

| | |
|---|--|
| Active ingredient (main ingredient) | tramadol hydrochloride |
| Other ingredients (inactive ingredients) | sodium acetate trihydrate water for injection |

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

What Tramadol Sandoz looks like

Tramadol Sandoz 100 mg/2 mL - clear colourless liquid, free of particles, packaged in clear glass ampoules. Available in boxes of 5 ampoules (AUST R 102013).

Who distributes Tramadol Sandoz

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

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