

## Consumer Medicine Information

### 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.

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Tramadol Sandoz.

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 using 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 IS USED FOR

This medicine is used to relieve severe pain.

It contains the active ingredient tramadol hydrochloride.

Tramadol hydrochloride belongs to a group of medicines called opioid analgesics (pain relievers).

**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 available only with a doctor's prescription.

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.

### BEFORE YOU USE TRAMADOL SANDOZ

#### When you must not use it

**Do not use 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 throat or other parts of the body
- skin rash, itching or hives on the skin

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

- you have respiratory disease or slow or shallow breathing
- regularly drink 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)
- taking medicines for depression known as monoamine oxidase inhibitors (MAOI) or have taken any within the last two weeks (e.g. Nardil, Parnate)
- have uncontrolled epilepsy or if your epilepsy is not well controlled by treatment
- 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 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.

#### 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 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 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.**

#### Before you start to use it

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

**Tell your doctor if you:**

- have a known allergy to Tramadol Sandoz or any of the ingredients listed at the end of this leaflet
- known to be sensitive to opioids
- drink alcohol
- have or ever had any other 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

- have or have had any problems with drug or alcohol dependence.

**Tell your doctor if you are pregnant or plan to become pregnant. Tramadol Sandoz is not recommended for use during pregnancy. Tramadol Sandoz can pass to your unborn baby when you are pregnant.**

**Tell your doctor if you are breastfeeding or plan to breast-feed.**

Tramadol Sandoz is not recommended for use 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 using Tramadol Sandoz.**

#### *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 may interfere with each other. These include:

- 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
- medicines for mental or psychiatric disorders including phenothiazines
- medicines to help you sleep
- medicines for irregular or rapid heart beats
- carbamazepine (eg. Tegretol)
- coumarin derivatives (e.g. warfarin: brand names are Coumadin or Marevan)
- some antibiotics.

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.

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

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## HOW TO 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.

#### *If you use too much (overdose)*

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.

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## WHILE YOU USING TRAMADOL SANDOZ

### *Things you must 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 you become pregnant while using this medicine, tell your doctor immediately.**

**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.**

### *Things you must 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.**

### *Things to be careful of*

**Be careful driving or operating machinery 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.

**Be careful when drinking alcohol while you are using this medicine.**

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

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## SIDE EFFECTS

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

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 are:**

- dizziness
- headache
- sedation, fatigue
- constipation

- nausea or vomiting
- sweating
- dry mouth

**The following side effects are less common:**

- changes in appetite
- indigestion
- hiccups
- skin reactions
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor
- seizures
- respiratory depression
- improvement in mood
- confusion
- anxiety
- sleep disturbance
- 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.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- skin rash (red spots or patches), itching, hives, skin lumps
- swelling or puffiness of the eyelids, face or lips, mouth or throat which may cause difficulty in swallowing
- breathing difficulties including chest tightness, chest pains and wheezing
- heart palpitations, faintness or collapse
- hallucinations
- convulsions.

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

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.

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

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

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## AFTER USING TRAMADOL SANDOZ

### *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.

Protect from light.

Do not store Tramadol Sandoz 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*

Return any unused or out of date medicine to your pharmacist.

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## PRODUCT DESCRIPTION

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### *What it looks like*

Tramadol Sandoz comes in one strength:

Tramadol Sandoz 100 mg/2 mL - clear colourless liquid, free of particles, packaged in clear glass ampoules.

Available in boxes of 5 ampoules.

### *Ingredients*

#### **Active ingredient:**

- Tramadol Sandoz 100 mg/2 mL - 100 mg tramadol hydrochloride in 2 mL.

#### **Inactive ingredients:**

- sodium acetate trihydrate
- water for injection.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Supplier*

Tramadol Sandoz 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

This leaflet was revised in February 2022.

#### **Australian Register Number**

100 mg/2 mL injection: AUST R 102013