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## Consumer Medicine Information

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### 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.

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### WHAT TRAMADOL SANDOZ IS USED FOR

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

This medicine is available only with a doctor's prescription.

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### 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:**

- regularly drink large quantities of alcohol
- 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 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.

**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 or have had any of the following medical conditions:**

- known to be sensitive to opioids
- drink alcohol every day
- diseases of the kidney, liver or pancreas
- severe stomach problems
- lung or breathing problems, such as asthma
- fits or convulsions/epilepsy
- head injury or severe headache
- drug, alcohol or substance dependence.

**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 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 ('s) and tricyclic anti-depressants ('s), or anti-psychotics
- 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 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.

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, confusion, breathing difficulty, 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 become pregnant while using this medicine, tell your doctor immediately.**

**Tell your doctor if you feel you do not need as much Tramadol Sandoz. Your doctor may adjust your dose.**

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

*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.**

*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, 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.

**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.**

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

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

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

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

- indigestion
- confusion
- anxiety
- muscle weakness
- tremor
- seizures
- respiratory depression
- 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, collapse.

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

**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 of the face, lips, mouth or throat which may cause difficulty in swallowing
- breathing difficulties including chest tightness, chest pains and wheezing
- heart palpitations, faintness or collapse
- fast or irregular heartbeats
- hallucination
- fits or convulsions
- Serotonin Syndrome: symptoms include fever, sweating, confusion, agitation, muscle twitching, 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.

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## AFTER USING TRAMADOL SANDOZ

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

Available in boxes of 5 ampoules.

### *Ingredients*

#### **Active ingredient:**

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

#### **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

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#### **Australian Register Number**

100mg/2mL injection: AUST R 102013