
Consumer Medicine Information

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 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 IS USED FOR

This medicine is used to relieve moderate to severe pain.

It contains the active ingredient tramadol.

Tramadol 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 available only with a doctor's prescription.

This medicine is very unlikely to be addictive if taken as prescribed by your doctor. However, if you take Tramadol Sandoz 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

When you must not take it

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

- tramadol, 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
- taking medicines for depression known as monoamine oxidase inhibitors (MAOI) or have taken any within the last two weeks
- treatment for drug or substance dependence.

Do not give this medicine to children.

There is no experience with the use of this medicine in children.

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:

- any lung or breathing problems
- any diseases of the kidney, liver or pancreas
- severe stomach problems
- a serious head injury
- any fits or convulsions/epilepsy
- 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 taking 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:

- carbamazepine (e.g. Tegretol)
- coumarin derivatives (e.g. warfarin: some brand names are Coumadin or Marevan)
- ondansetron
- medicines for irregular or rapid heart beat
- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- 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 taking this medicine.

HOW TO TAKE TRAMADOL SANDOZ

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

For moderate pain, one Tramadol Sandoz capsule may be enough for the first dose, followed by one or two capsules two or three times a day as required.

For moderate to severe pain, two Tramadol Sandoz capsules are usually required for the first dose, followed by one or two capsules every four to six hours as required.

Patients over 75 years of age may require a lower daily dose.

Do not take more than eight Tramadol Sandoz capsules per day.

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 may not work as well and your problem may not improve.

How to take it

Swallow the capsules whole with a full glass of water.

When to take Tramadol Sandoz

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

Depending on the medical condition for which you require this medicine, your doctor may tell you to take it for only a day or two or longer, up to a few months or more.

If you forget to take it

Take your dose as soon as you remember. The next dose should be taken after four or six hours, or as prescribed by your doctor.

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 13 11 26) 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. 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

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.

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.

If your pain is not severe and you feel that you do not need as much Tramadol Sandoz as your doctor ordered, consult your doctor.

Tell your doctor if your pain gets worse. Do not take extra doses without checking with your doctor.

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.

Things you must not do

Do not take 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 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.

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:

Common side effects:

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

Less common side effects:

- indigestion
- changes in appetite
- skin reactions
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor

- seizures
- respiratory depression
- improvement in mood
- confusion
- sleep disturbance
- blurred vision
- difficulty in passing urine.

Serotonin Syndrome: signs of this vary and are not specific: they may include fever, sweating, confusion, agitation, diarrhoea, muscle twitching, difficulty with walking and balance. 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
- chest tightness, wheezing or pain in the chest
- heart palpitations, faintness or collapse
- hallucinations
- convulsions.

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

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. If ambient temperatures above 30°C and/or high humidity are likely to be experienced during ongoing storage, a cool, dry place should be sought to keep this medicine.

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

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 capsules come in one strength:

Tramadol Sandoz 50mg - capsules with a yellow body and a green cap.

Available in blister packs of 20 capsules.

Ingredients

Active ingredient:

- Tramadol Sandoz 50mg - 50mg tramadol hydrochloride.

Inactive ingredients:

- croscarmellose sodium
- povidone
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate
- gelatin
- titanium dioxide
- quinoline yellow
- iron oxide yellow
- brilliant blue FCF.

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

Supplier

Sandoz Pty Ltd
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Macquarie Park, NSW 2113
Australia
Tel: 1800 634 500

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50mg capsules: AUST R 141240 (blisters)