

# TRAMADOL-WGR SR

## 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 taking TRAMADOL-WGR SR?

TRAMADOL-WGR SR contains the active ingredient tramadol hydrochloride. TRAMADOL-WGR SR is used to relieve moderate to severe pain. For more information, see Section [1. Why am I taking TRAMADOL-WGR SR?](#) in the full CMI.

### 2. What should I know before I take TRAMADOL-WGR SR?

Do not use if you have ever had an allergic reaction to tramadol hydrochloride, any other opioid 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 take TRAMADOL-WGR SR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TRAMADOL-WGR SR 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 take TRAMADOL-WGR SR?

- The recommended dosage is: 1 or 2 TRAMADOL-WGR SR 100 mg tablet(s) twice a day (morning and evening); **OR** 1 TRAMADOL-WGR SR 150 mg or 200 mg tablet twice a day (morning and evening).
- As all patients, especially the elderly (> 75 years of age) respond to treatment differently, your doctor may start you on a lower dose. Continue taking your medicine for as long as your doctor tells you.
- Do not take more than four of the 100 mg tablets per day, **OR** more than two of the 150 mg or of the 200 mg tablets per day.
- Swallow the tablets whole with a full glass of water. They must NOT be chewed, crushed or dissolved.

More instructions can be found in Section [4. How do I take TRAMADOL-WGR SR?](#) in the full CMI.

### 5. What should I know while taking TRAMADOL-WGR SR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using TRAMADOL-WGR SR tablets.</li><li>• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>• If your pain lessens or gets worse, consult your doctor.</li><li>• If you are about to have any blood tests, tell your doctor that you are taking this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take TRAMADOL-WGR SR to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how TRAMADOL-WGR SR affects you.</li><li>• This medicine may cause dizziness or drowsiness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not take this medicine if have had large amounts of alcohol or other substances which affect consciousness.</li><li>• Tell your doctor if you drink alcohol every day.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the pack until it is time to take them, and in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while taking TRAMADOL-WGR SR?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include dizziness, sedation, fatigue, lack of energy, headache, constipation, nausea, vomiting, sweating, or dry mouth. Serious side effects include indigestion, changes in appetite, skin reactions, sudden onset of low blood pressure, collapse, muscle weakness, tremor, seizures, respiratory depression, changes in mood or behaviour, confusion, delirium, anxiety, change in sensations such as pricking or tingling, sleep disturbance, blurred vision or changes to the eye, slow or fast heartbeat, difficulty in passing urine, sweating, agitation, muscle twitching, spontaneous muscle contraction, tremor, high body temperature. Signs of an allergic reaction may include: skin rash or lumps, itching hives, swelling of the eyelids, face or lips; chest tightness or pain, wheezing, shortness of breath, difficulty breathing, heart palpitations, faintness or collapse; hallucinations; convulsions.

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-WGR SR 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-WGR SR poses risks 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-WGR SR 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-WGR SR 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-WGR SR**

Using TRAMADOL-WGR SR 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-WGR SR.

# TRAMADOL-WGR SR

**Active ingredient: tramadol hydrochloride**

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking TRAMADOL-WGR SR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TRAMADOL-WGR SR.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking TRAMADOL-WGR SR?

TRAMADOL-WGR SR contains the active ingredient **tramadol hydrochloride**. Tramadol hydrochloride belongs to the group of medicines called analgesics (pain relievers).

TRAMADOL-WGR SR is used to relieve moderate to severe pain. TRAMADOL-WGR SR tablets are designed to release the pain reliever gradually over several hours.

TRAMADOL-WGR SR tablets are not usually addictive. However, rarely, addiction to tramadol has been reported.

## 2. What should I know before I take TRAMADOL-WGR SR?

### Warnings

**Do not take TRAMADOL-WGR SR if you:**

- are allergic to tramadol hydrochloride, or any other opioids such as morphine or 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 or other parts of the body; rash, itching or hives on the skin.
- have taken large amounts of alcohol or other substances which can affect your level of consciousness;
- are taking medicine for depression containing a "monoamine oxidase inhibitor" also known as MAOI, or have taken any within the past two weeks. Examples of MAOI - containing medicines are Nardil, Parnate;
- are having treatment for withdrawal from narcotics;
- have epilepsy that is not under control.

**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.

### Check with your doctor if you:

- are known to be sensitive to opioids.
- drink alcohol every day
- you have, or have had, any drug or alcohol dependence
- have allergies to any other medicines, foods, preservatives or dyes
- have any lung or breathing problems
- have had fits or convulsions or epilepsy
- have any disorder of the kidney, liver or pancreas
- have any stomach problems
- have severe headaches or have had a head injury
- you have galactose intolerance, or lactase deficiency or glucose- galactose malabsorption
- sleep related breathing disorders
- have any other medical conditions
- take any medicines for any other condition

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?](#)

**Tell your doctor if you think you may require long term use of TRAMADOL-WGR SR.**

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

TRAMADOL-WGR SR is not recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits involved.

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

TRAMADOL-WGR SR is not recommended for use during breast feeding. Your doctor can discuss with you the risks and benefits involved.

### 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-WGR SR may interfere with each other. These include:

- carbamazepine (eg. Tegretol®);
- coumarin derivatives (eg. Warfarin: some Brand names are Coumadin®, or Marevan®);
- medicine for irregular or rapid heartbeat;
- medicines for depression (mirtazapine), tricyclic anti-depressants (eg. Sinequan, Allegron), selective serotonin reuptake inhibitors (SSRI's) (eg. Prozac, Zoloft), serotonin noradrenaline reuptake inhibitors (SNRI's) (eg. Efexor, Cymbalta), MAOI (eg. Nardil, Parnate), bupropion (Zyban);
- 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-WGR SR or may affect how well it works. You may need different amounts of your medicine, 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-WGR SR.**

### 4. How do I take TRAMADOL-WGR SR?

#### How much to take

- The recommended dosage of TRAMADOL-WGR SR is either:
  - one or two TRAMADOL-WGR SR 100 mg tablet(s) twice a day (morning and evening); **OR**
  - one TRAMADOL-WGR SR 150 mg or 200 mg tablet twice a day (morning and evening).
- As all patients respond to treatment differently, your doctor may start you on a lower dose.
- Do not take more than four of the 100 mg tablets per day **OR** more than two of the 150 mg or of the 200 mg tablets per day.
- Patients over 75 years may need a reduced daily dose of TRAMADOL-WGR SR compared to younger adults.
- 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 on the box, ask your doctor or pharmacist for help.

#### How to take TRAMADOL-WGR SR

**Swallow the tablets whole with a full glass of water.**

**The tablets must NOT be chewed, crushed or dissolved.**

This will release all the analgesic quite quickly. Side effects may then occur.

#### When to take TRAMADOL-WGR SR

TRAMADOL-WGR SR may be taken, before, with, or after food usually in the morning and evening.

Continue taking your medicine for as long as your doctor tells you. This differs between individuals depending on how severe your pain is, how you respond to TRAMADOL-WGR SR, and the cause of your pain.

Ask your doctor for advice on how long you need to take TRAMADOL-WGR SR tablets.

#### If you forget to take TRAMADOL-WGR SR

If you forget to take one dose, take the dose when you remember. The following dose should be taken after twelve hours, or as prescribed by your doctor.

**Do not take a double dose to make up for the dose that you missed.**

**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 TRAMADOL-WGR SR**

If someone takes an overdose, they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

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 think that you have used too much TRAMADOL-WGR SR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include decrease in breathing and fits or convulsions.

## **5. What should I know while taking TRAMADOL-WGR SR?**

### **Things you should do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TRAMADOL-WGR SR tablets.**

**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-WGR SR 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 should not do**

Do not take TRAMADOL-WGR SR tablets 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.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TRAMADOL-WGR SR affects you.**

TRAMADOL-WGR SR may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Ask your doctor for advice about whether it is safe for you to drive or operate machinery while taking TRAMADOL-WGR SR tablets.

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Do not take TRAMADOL-WGR SR tablets if you have had large amounts of alcohol or other substances which affect consciousness.

### **Looking after your medicine**

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a place where the temperature stays below 25°C.

Follow the instructions on 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.**

### **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"><li>dizziness;</li><li>sedation, fatigue or lack of energy;</li><li>headache;</li><li>constipation;</li><li>nausea, vomiting;</li><li>sweating;</li><li>dry mouth.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>indigestion;</li><li>changes in appetite;</li><li>skin reactions;</li><li>sudden onset of low blood pressure, collapse;</li><li>muscle weakness;</li><li>tremor;</li><li>seizures;</li><li>respiratory depression;</li><li>improvement or changes in mood or behaviour;</li><li>confusion, delirium, anxiety;</li><li>change in sensations such as pricking or tingling;</li><li>sleep disturbance;</li><li>blurred vision or changes to the eye;</li><li>slow or fast heartbeat;</li><li>difficulty in passing urine;</li><li>serotonin syndrome: symptoms may vary and are not specific; they may include sweating, agitation, muscle twitching, spontaneous muscle contraction, tremor, high body temperature. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.</li><li>allergic reaction: symptoms may include: 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; shortness of breath, difficulty breathing; heart palpitations, faintness or collapse; hallucinations; or convulsions.</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**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](http://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-WGR SR contains

<b>Active ingredient (main ingredient)</b>	tramadol hydrochloride
<b>Other ingredients (inactive ingredients)</b>	calcium hydrogen phosphate dihydrate hypolose colloidal anhydrous silica magnesium stearate.

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

### What TRAMADOL-WGR SR looks like

TRAMADOL-WGR SR 100 mg – off-white, round biconvex tablet plain on both sides. (AUST R 439651)

TRAMADOL-WGR SR 150 mg – off-white, capsule shaped tablet plain on both sides. (AUST R 439652)

TRAMADOL-WGR SR 200 mg – off-white, capsule shaped tablet plain on both sides. (AUST R 439653)

All tablets are contained in a blister pack within a carton.

### Who distributes TRAMADOL-WGR SR

Wagner Pharmaceuticals Pty Ltd  
6 Albert Street  
Preston, Victoria, 3072  
Tel: 1800 936 140

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