

# GenRx Tramadol

contains the active ingredient, tramadol (TRA-ma-dole) hydrochloride

## Consumer Medicine Information

**For a copy of a large print leaflet, Ph: 1800 195 055**

### What is in this leaflet

**Read this leaflet carefully before taking your medicine Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.**

This leaflet answers some common questions about tramadol.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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.

**Keep this leaflet with your medicine.**

You may need to read it again.

### What tramadol is used for

The name of your medicine is GenRx Tramadol. It contains the active ingredient tramadol hydrochloride.

Tramadol is used to relieve moderate to severe pain. It belongs to a group

of medicines called analgesics (pain relievers).

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Tramadol is not normally addictive, although some cases have been reported.

#### **Use in children**

There is not enough information to recommend the use of this medicine in children under 12 years of age.

### Before you take tramadol

#### **When you must not take it**

**Do not take this medicine if you have had an allergic reaction to:**

- tramadol or any other medicine containing tramadol.
- any of the ingredients listed at the end of this leaflet.
- any medicines known as opioid (such as morphine or 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; or rash, itching or hives on the skin.

**Do not take tramadol if you:**

- are taking any medicines for depression which contain a "monoamine oxidase inhibitor" (MAOI), or you have taken such a medicine within the last 14 days.
- have recently taken large amounts of alcohol or other substances that can affect your level of alertness.
- have epilepsy which is not completely under control.

**Do not take this medicine after the expiry date (EXP) printed on the pack**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.**

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:**

1. have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
2. drink alcohol every day.
3. have, or have had, any problems with drug or alcohol dependence.

**4. have, or have had, any health problems, including the following:**

- any lung or breathing problems
- serious head injury
- any diseases of the kidney, liver or pancreas
- severe abdominal or stomach problems
- any seizures, fits or convulsions/epilepsy.

**5. are pregnant or plan to become pregnant.**

Tramadol is not recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits of taking tramadol during pregnancy.

**6. are breast-feeding or plan to breast-feed.**

Tramadol is not recommended for use during breast-feeding. Your doctor can discuss with you the risks and benefits of taking tramadol when breast-feeding.

**If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.**

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

- certain medicines used to treat depression, sleeplessness or mental conditions (such as MAOIs, selective serotonin reuptake inhibitors (SSRIs), tricyclic anti-depressants, phenothiazines or anti-psychotics)
- CNS depressants (such as opioids, tranquillisers or sedative hypnotics)
- carbamazepine, a medicine mainly used to treat epilepsy

- coumarin derivatives (such as warfarin)
- some antibiotics.

These medicines may be affected by tramadol 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 can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking tramadol.

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**How to take this medicine**

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Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

***How much to take***

Your doctor or pharmacist will tell you how many capsules you will need to take.

**For moderate pain:**

The usual adult dose is one or two capsules taken two or three times daily.

One capsule (50 mg) may be enough for the first dose.

**For moderate to severe pain:**

The usual adult dose is one or two capsules, every four to six hours.

Two capsules (100 mg) are usually required for the first dose.

**Do not take more than eight capsules (400 mg) per day.**

**If you are over 75 years of age, do not take more than six capsules (300 mg) per day, as you may require a lower daily dose.**

***How to take it***

Swallow the capsules whole with a glass of water.

***When to take it***

It does not matter if you take tramadol before, with or after food.

***How long to take it***

Continue taking your medicine for as long as your doctor tells you.

The number of doses you take each day, the time between doses and the length of time you take tramadol depends on the medical condition for which you are taking this medicine. Your doctor may tell you to take it for only a day or two - or it may be longer, up to a few months or more.

***If you forget to take it***

If you forget to take a dose, and it is more than 4-6 hours until your next dose is due, take your missed dose as soon as you remember. Then continue taking your medicine as you normally would.

If it is less than 4-6 hours until your next dose is due, skip the dose you missed and take your next dose when you are meant to.

**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.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may result in breathing difficulties and convulsions (fits).

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## **While you are taking tramadol**

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### ***Things you must do***

If you become pregnant while you are taking this medicine, tell your doctor immediately.

If your pain gets worse, tell your doctor. Do not take extra doses without checking with your doctor.

If your pain is not severe and you feel that you do not need to take as much tramadol as your doctor prescribed, let them know. Your doctor may adjust your dose.

If you are having any medical tests, tell your doctor that you are taking this medicine, as tramadol may affect the results of some tests.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking tramadol.

Tell any other doctors, dentists and pharmacists who treat you that you are taking tramadol.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine, as tramadol may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

### ***Things you must not do***

Do not take tramadol to treat any other complaints unless your doctor tells you to.

Do not give tramadol 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 this medicine affects you. Tramadol may make some people dizzy or drowsy.

Be careful when drinking alcohol while you are taking this medicine. It is best not to drink alcohol when you are taking tramadol as side effects may be worse.

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## **Side effects of tramadol**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine. Tramadol helps most people with moderate to severe pain, but it may have unwanted side effects in a few people.

All medicines can have side effects. If side effects occur with tramadol, they are most likely to be minor and temporary. However, sometimes they are serious and need medical attention.

If you are over 75 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Other side effects not listed below may also occur in some people. Tell your doctor if you notice anything else that is making you feel unwell.

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
- drowsiness
- dry mouth
- sweating
- headache
- physical weakness or loss of strength

- fatigue
- nausea or vomiting
- constipation.

### **Less common side effects:**

- indigestion and stomach pain
- diarrhoea
- flatulence
- skin reactions
- low blood pressure suddenly starting; collapse
- fast heart beat
- hot flushes
- tremors/shakes.

### **Rare side effects:**

- increase in blood pressure
- slow heart beat
- shortness of breath
- changes in appetite
- changes in mood
- confusion
- sleep disturbances
- muscle weakness
- difficulty in breathing
- difficulty in passing urine
- blurred vision.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. These side effects are very serious:**

- 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, fainting or collapse
- hallucinations
- seizures.

### ***Can tramadol be addictive?***

When tramadol is taken as prescribed by your doctor, addiction to it is unlikely.

If you are taking tramadol for a longer time, your body may become

used to it and mild withdrawal symptoms may occur if you suddenly stop taking it.

Therefore, it is very important to take this medicine as directed by your doctor. Your dose may need to be gradually reduced. Do not suddenly stop taking this medicine.

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## After taking this medicine

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### **Storage**

**Keep your medicine in its original packaging until it is time to take them.**

If you take the capsules out of their original packaging they may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store your medicine, 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.

### **Where to go for further information**

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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## Product description

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### **What GenRx Tramadol looks like**

The colour of each capsule is white to off-white.

They are available in packs of 6 and 20 capsules.

### **Ingredients**

Each capsule contains 50 mg of tramadol hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- anhydrous calcium hydrogen phosphate
- magnesium stearate
- colloidal anhydrous silica
- titanium dioxide
- gelatin.

This medicine is lactose-free, sucrose-free, gluten-free, tartrazine-free and free of other azo dyes.

### **Australian Registration Number**

GenRx Tramadol 50 mg Capsules:  
AUST R 97458

### **Sponsor**

Apotex Pty Ltd  
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Australia

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This leaflet was prepared in:  
July 2008.