

TRAMADOL SR GENERICHEALTH

tramadol hydrochloride

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 being given Tramadol SR generichealth against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine. You may need to read it again.

What Tramadol SR generichealth is used for

Tramadol SR generichealth is used to relieve moderate to severe pain. It belongs to the group of medicines called analgesics (pain relievers). Tramadol SR generichealth tablets are designed to release the active ingredient for pain relief gradually over several hours.

Before you take Tramadol SR generichealth

Tell your doctor if:

- you are allergic to any of the ingredients in Tramadol SR generichealth (see "Product Description").
- you are known to be sensitive to opioids.
- you have lung or breathing problems.
- you are taking any medicines for depression, or mental or psychiatric disorder or to help you sleep.
- you are taking medication known as selective serotonin reuptake inhibitors (SSRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti psychotics.
- you have had any fits or convulsions, or take medicines for epilepsy.
- you are taking the medicine carbamazepine (one brand name is Tegretol).
- you have any disorder of the kidney, liver or pancreas, including any related to alcohol intake - for example, cirrhosis of the liver.
- you have a stomach problem.
- you have a severe headache or have had a head injury.
- you have, or have had, any drug or alcohol dependence.
- you are taking any other medicine, including those you buy from a pharmacy or supermarket.

Use in Children

Tramadol SR generichealth is not recommended for children under 12 years.

Use in the Elderly

Patients over 75 years may need a reduced daily dose of Tramadol SR generichealth compared to younger adults.

If you are pregnant or intend to become pregnant

Tramadol SR generichealth is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using Tramadol SR generichealth during pregnancy.

If you are breast-feeding or plan to breast-feed

Tramadol SR generichealth is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits using Tramadol SR generichealth when breast-feeding.

If you are driving or operating machinery

Tramadol SR generichealth may make you drowsy or dizzy. Ask your doctor or pharmacist for advice about whether it is safe for you to drive or operate machinery while taking Tramadol SR generichealth.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Tramadol SR generichealth. These include:

- carbamazepine (eg. Tegretol);
- coumarin derivatives (eg. Warfarin, some brand names are Coumadin or Marevan);
- ondansetron;
- medicine for irregular or rapid heartbeat;
- medicines for depression, sleeplessness or mental conditions such as selective serotonin re-uptake inhibitors (SSRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics;
- some antibiotics.

These medicines may be affected by Tramadol SR generichealth, 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tramadol SR generichealth.

When not to take it

- you have an allergy to any of the ingredients (see "Product Description" for details).
- you have an allergy to any other medicines known as opioid analgesics, eg. morphine or codeine.

- you have taken large amounts of alcohol or other substances which can affect your level of consciousness.
- you 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.
- you are having treatment for withdrawal from narcotics.
- the packaging is torn or shows signs of tampering.
- any tablets look damaged or discoloured.
- it is after the expiry date which is printed on the carton.

How to take Tramadol SR generichealth

How much to take

The recommended dosage of Tramadol SR generichealth is either:

- one or two Tramadol SR generichealth 100 mg tablet(s) twice a day (morning and evening) OR
- one Tramadol SR generichealth 150 mg or 200 mg tablet twice a day (morning and evening).

Do not take more than four of the 100 mg tablets per day.

Do not take more than two of the 150 mg or of the 200 mg tablets per day.

How to take it

Tramadol SR generichealth tablets should be swallowed whole with water. They may be taken before, with, or after food.

They must NOT be chewed, crushed or dissolved. This will release all active ingredient for pain relief quite quickly. Side effects may then occur.

How long to take it for

This varied from individual to individual. It depends, for example, on how severe your pain is, how you respond to Tramadol SR generichealth, and the cause of your pain. Ask your doctor for advice on how long you need to take Tramadol SR generichealth tablets.

As with all medicines:

- take only as your doctor has told you.
- if you feel that you do not need as much Tramadol SR generichealth as your doctor has prescribed for you, talk to your doctor.
- tell your doctor if your pain is not helped or gets worse. Do not take increased amounts or extra doses of Tramadol SR generichealth unless your doctor advises you to.

If you take too much

In the event of overdose, you should contact your nearest Poisons Information Centre (phone: 131 126), doctor or hospital emergency department immediately.

Overdosage with Tramadol SR generichealth will result in a decrease in breathing and fits or convulsions.

While you are taking Tramadol SR generichealth

If you forget to take it

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.

Is Tramadol SR generichealth addictive

When used as prescribed by your doctor, addiction to Tramadol SR generichealth is very unlikely.

If you are taking Tramadol SR generichealth for a prolonged period of time, your body may become used to the medicine and mild withdrawal symptoms may occur if you suddenly stop taking the medicine.

It is important therefore to take Tramadol SR generichealth only as directed by your doctor.

Side Effects

All medicines can cause unwanted effects, and some side effects have been reported with Tramadol SR generichealth. Side effects reported with Tramadol SR generichealth are usually minor and temporary, but some may be serious.

The most common side-effects of Tramadol SR generichealth are:

- dizziness;
- sedation, fatigue;
- headache;
- constipation;

- nausea, vomiting;
- sweating;
- dry mouth.

The following side-effects are less common:

- indigestion;
- changes in appetite;
- skin reactions;
- sudden onset of low blood pressure, collapse;
- muscle weakness;
- tremor;
- seizures;
- respiratory depression;
- improvement of 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.

This is not a complete listing. Occasionally, other side effects may be experienced.

Tell your doctor immediately if you experience any of the following side effects, as urgent medical treatment may be required:

- 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.

If you experience any side-effects that have not been mentioned here, consult your doctor or pharmacist as soon as possible.

You should remember that all medicines carry some risks. It is possible that some risks might not yet have been detected despite many years of experience with the medicine.

How to store Tramadol SR generichealth

- Keep Tramadol SR generichealth in a safe place, where children cannot reach it.
- Store in a cool, dry place, below 25°C.
- Keep away from direct sunlight.
- Do not use Tramadol SR generichealth after the use-by-date printed on the carton.

Product description

What Tramadol SR generichealth tablets look like

Tramadol SR generichealth 100 mg: Off-white, round biconvex tablet plain on both sides
Tramadol SR generichealth 150 mg: Off-white, capsule shaped tablet plain on both sides
Tramadol SR generichealth 200 mg: Off-white, capsule shaped tablet plain on both sides

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

Ingredients

Active ingredient:

- Tramadol hydrochloride

Inactive ingredients:

- Calcium hydrogen phosphate
- Hydroxypropylcellulose
- Silica – colloidal anhydrous
- Magnesium stearate

Sponsor

Southern Cross Pharma Pty
Ltd
Suite 5/118, Church St
Hawthorn, VIC, 3122

Distributed in Australia by

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell VIC 3124

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150 mg: AUST R 194540
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200 mg: AUST R 194541

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