

Tramedo SR

Tramadol hydrochloride modified release tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tramedo SR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Tramedo SR against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Tramedo SR is used for

Tramedo SR is used to relieve moderate to severe pain.

Tramedo SR belongs to a group of medicines called analgesics, also known as "pain relievers" or "pain killers".

Tramedo SR tablets are designed to release the pain reliever gradually over several hours.

Ask your doctor if you have any questions about why Tramedo SR has been prescribed for you.

Your doctor may have prescribed Tramedo SR for another reason.

Tramedo SR is not recommended for use in children below 12 years, as its safety and effectiveness has not been established in this age group.

Tramedo SR is available only with a doctor's prescription.

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

Before you take Tramedo SR

When you must not take it

Do not take Tramedo SR if you:

- have a known allergy to tramadol
- have an allergy to other medicines known as opioid analgesic, e.g. morphine or codeine
- have a known allergy to any of the ingredients listed at the end of this leaflet
- are taking medicine for depression containing a monoamine oxidase inhibitor (MAOI) or have taken a MAOI within the past two weeks
- are having treatment for withdrawal from narcotics.

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 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 Tramedo SR, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are known to be sensitive to opioids.

Tell your doctor if you drink alcohol every day.

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
- severe headaches or have had a serious head injury
- any fits or convulsions/epilepsy
- drug or alcohol dependence

Tell your doctor if you are pregnant or plan to become pregnant.

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

Tell your doctor if you are breastfeeding or wish to breastfeed.

Tramedo SR is not recommended for use during breastfeeding, as it passes into breast milk and may affect your baby.

Your doctor may want to take special care if you have any of these conditions.

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

Taking other medicines

Do not take Tramedo SR if you are taking any monoamine oxidase inhibitors (MAOIs).

Wait at least 14 days after stopping your MAOI before starting Tramedo SR.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Tramedo SR, or may affect how well it works. These include:

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

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Tramedo SR.

How to take Tramedo SR

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

They may differ from the information contained in this leaflet.

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

How much to take

The recommended dosage of Tramedo SR is either:

- one or two Tramedo SR 100 mg tablet(s) twice a day (morning and evening)

OR

- one Tramedo SR 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.

The dose varies from person to person.

Your doctor will decide the right dose for you. This may depend on your condition, age, other medicines you are taking and how you respond to Tramedo SR.

Tramedo SR is not recommended for use in children below 12 years of age.

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

How to take it

Tramedo SR tablets should be swallowed whole with water.

They must NOT be chewed, crushed or dissolved. This will release all the analgesic quite quickly. Side-effects may then occur.

When to take it

Tramedo SR maybe taken, before, with, or after food.

How long to take it for

Keep taking Tramedo SR for as long as your doctor tells you to.

Your length of treatment will depend on the medical condition for which you require Tramedo SR and your response to it.

Tramedo capsules are also available and they provide moderate to severe pain relief.

If you forget to take it

If you forget to take a dose, take it as soon as 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 you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Tramedo SR.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Tramedo SR, you may have trouble breathing, lose consciousness or have fits or seizures.

While you are taking Tramedo SR

Things you must do

If you become pregnant while taking Tramedo SR, tell your doctor immediately.

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

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

If you are going to have surgery (including dental surgery), tell the

surgeon or anaesthetist that you are taking this medicine.

Talk to your doctor if you feel that you do not need to take as much Tramedo SR as ordered, because your pain is relieved.

If you have been taking Tramedo SR for a prolonged period of time, your body may have become used to the medicine. If you stop taking it suddenly, you may get some unwanted side effects.

Your doctor will tell you how to gradually reduce the amount of Tramedo SR you are taking before stopping completely.

If you feel that your pain gets worse or is not relieved at the dose prescribed, do not take extra doses without checking with your doctor.

Your doctor will advise you on what to do.

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.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not drive or operate machinery until you know how Tramedo SR affects you.

Tramedo SR can cause drowsiness, dizziness or fatigue in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Do not use this medicine to treat any other conditions unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same conditions as you.

Things to be careful of

Be careful when drinking alcohol while taking Tramedo SR.

Combining Tramedo SR and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol

while being treated with Tramedo SR.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tramedo SR.

Tramedo SR relieves pain in most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

Common side effects:

- dizziness
- sedation, fatigue
- headache
- constipation
- nausea, 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 of mood
- confusion
- sleep disturbance
- blurred vision
- difficulty in passing urine

- Serotonin Syndrome: signs of this vary and are not specific: they may include sweating, agitation, muscle twitching, tremor, spontaneous muscle contraction, high body temperature. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.

The above list includes common and mild side effects of Tramedo SR.

See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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

The side effects listed above are very serious and may require urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people.

After taking Tramedo SR

Storage

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 tablet in a cool dry place where the temperature stays below 25°C.

Do not store Tramedo SR 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 Tramedo SR, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Tramedo SR is available in three strengths:

- Tramedo SR 100 tablets are almost white, round, biconvex, marked with TL 100 on one side.
- Tramedo SR 150 tablets are almost white, oval, marked with TL 150 on one side.
- Tramedo SR 200 tablets are almost white, oval, marked with TL 200 on one side.

Each pack contains 20 tablets.

Ingredients

The active ingredient in Tramedo SR is tramadol hydrochloride.

- Each Tramedo SR 100 tablet contains 100 mg of tramadol hydrochloride.
- Each Tramedo SR 150 tablet contains 150 mg tramadol hydrochloride
- Each Tramedo SR 200 tablet contains 200 mg of tramadol hydrochloride

The Tramedo SR tablets also contain the following inactive ingredients:

- glyceryl behenate

- calcium hydrogen phosphate dihydrate
- povidone
- silica-colloidal anhydrous

Tramedo SR tablets are lactose free.

Supplier

Tramedo SR is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Australian registration number:

Tramedo SR 100 AUST R 133147

Tramedo SR 150 AUST R 133157

Tramedo SR 200 AUST R 133158.

This leaflet was prepared on 05 July 2017.

Tramedo SR_cmi\Jul 17/00