

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.

The information supplied in this leaflet relates only to Tramedo SR Tablets.

It is not to be used in relation to any other product, which may also contain the same active ingredient.

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 are:

- * sensitive to opioids
- * allergic to any other medicines containing tramadol hydrochloride (eg. Tramal)
- * allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Tramedo SR if you have uncontrolled epilepsy or if you feel your epilepsy medicine is not working properly

Do not take Tramedo SR if you are taking a monoamine oxidase inhibitor (MAOI), or have taken a MAOI within the last 14 days.

Stop taking MAOIs at least 14 days before starting Tramedo SR.

Ask your doctor or pharmacist if you are unsure if you are taking, or have been taking a MAOI.

MAOIs are medicines used to treat depression and symptoms of Parkinson's disease.

Do not take Tramedo SR if you:

- * have drunken enough alcohol to make you feel woozy or drunk
- * feel "high" or "excited" because you have taken sedatives or sleeping pills, psychotropics (medicines that affect mood and emotions) or other pain relievers.

Do not take Tramedo SR after the expiry date (EXP) printed on the pack.

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

Do not take Tramedo SR if the packaging shows signs of tampering or the tablets do not look quite right.

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 pregnant or plan to become pregnant.

There is very little information on the safety of Tramedo SR during pregnancy. Therefore, Tramedo SR is not recommended for use 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.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * severe stomach problems
- * lung or breathing problems
- * head injury or a condition where there is increased pressure within the head
- * liver and/or kidney problems
- * drug or alcohol dependence problems
- * fits, convulsions/epilepsy or seizures.

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

Tell your doctor if you plan to have surgery that requires a general anaesthetic.

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:

- * medicines that help you to sleep or treat anxiety
- * other pain relievers
- * medicines used to treat mental illness or psychotic conditions
- * selective serotonin reuptake

inhibitors (SSRIs) and tricyclic antidepressants, medicines used to treat depression and/or other conditions

- * coumarin derivatives such as warfarin (eg. Coumadin, Marevan)
- * carbamazepine (eg. Tegretol, Teril)
- * quinidine (Kinidin Durules)
- * 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 Tramedo SR (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 and 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.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Tramedo SR.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Tramedo SR.

If you plan to have surgery (that needs a general anaesthetic), including dental surgery, tell your doctor or dentist that you are taking Tramedo SR.

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.

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 Tramedo SR to treat any other conditions unless your doctor tells you to.

Do not give Tramedo SR 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:

- * nausea, vomiting
- * constipation
- * dizziness, drowsiness, headache
- * sweating
- * fatigue, tiredness
- * dry mouth.

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

See your doctor as soon as possible if you notice any of the following:

- * confusion
- * difficulty in passing urine, pain with passing of urine or passing no urine
- * blurred vision
- * symptoms of Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea, muscle spasms, unsteadiness when walking.

Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of Tramedo SR with other medicines, such as SSRIs (see Taking other medicines section).

The above list includes serious side effects which may require medical attention.

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

- * symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- * symptoms of "shock" such as rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- * fast heart beat

- * worsening of asthma or breathing problems
- * fits or seizures
- * seeing, hearing or feeling things that are not there (hallucinations).

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 Tramedo SR 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.

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

If you take the tablets out of the bottle they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store Tramedo SR or any other medicine in the bathroom or near a sink.

Do not leave Tramedo SR in the car or on window sills.

Heat and dampness can destroy some 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
- * 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)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

Tramedo SR 100 AUST R 133147

Tramedo SR 150 AUST R 133157

Tramedo SR 200 AUST R 133158.

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