

APO-TRAMADOL SR

Modified Release Tablets

Tramadol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APO-TRAMADOL 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 risks and benefits. Your doctor has weighed the risks of you taking APO-TRAMADOL SR against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What APO-TRAMADOL SR is used for

APO-TRAMADOL SR is used to relieve moderate to severe pain.

It belongs to the group of medicines called analgesics (pain relievers).

APO-TRAMADOL SR tablets are designed to release the pain reliever gradually over several hours.

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

Your doctor may have prescribed it for another reason.

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

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

Before you take APO-TRAMADOL SR

When you must not take it

Do not take APO-TRAMADOL SR if you have an allergy to:

- any medicine containing tramadol hydrochloride.
- any of the ingredients listed at the end of this leaflet.
- any other medicines known as opioid analgesics, e.g. 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 or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you

- 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.

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 have allergies to any other medicines, foods, preservatives or dyes.

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

Tell your doctor if you drink alcohol everyday.

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

- any lung or breathing problems
- fits or convulsions/epilepsy
- any disorder of the kidney, liver or pancreas
- any stomach problems
- severe headaches or have had a head injury
- you have, or have had, any drug or alcohol dependence
- you have galactose intolerance, or lactase deficiency or glucose- galactose malabsorption
- sleep related breathing disorders

Tell your doctor if you think you may require long term use of APO TRAMADOL.

You may require careful monitoring.

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

APO-Tramadol SR is not recommended for use during pregnancy.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast feeding or plan to breast feed.

APO-TRAMADOL SR is not recommended for use during breast feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking APO-TRAMADOL SR.

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 APO-TRAMADOL SR may interfere with each other. 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 (mirtazapine), tricyclic anti-depressants (e.g. Sinequan, Allegron), selective serotonin reuptake inhibitors (SSRI's) (e.g. Prozac, Zoloft), serotonin noradrenaline reuptake inhibitors (SNRI's) (e.g. Efexor, Cymbalta), MAOI (e.g. Nardil, Parnate), bupropion (Zyban)
- medicines for sleeplessness (e.g. Temaze)
- quinidine, medicine used to treat abnormal heart rhythms
- anti-psychotics or phenothiazines (e.g. Risperdal, Clozaril)
- medicines for pain (e.g. tetrahydrocannabinol, buprenorphine (Subutex), pentazocine)
- medicines for seizures (carbamazepine, eg. Tegretol)
- some antibiotics.
- ketoconazole, an antifungal medicine

These medicines may be affected by APO-TRAMADOL SR or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Other interactions not listed above may also occur.

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

How to take APO-TRAMADOL SR

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 much to take

The recommended dosage of APO-TRAMADOL SR is either:

- one or two APO-TRAMADOL SR 100 mg tablet(s) twice a day (morning and evening)
OR
- one APO-TRAMADOL 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.

Do not take 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 APO-Tramadol SR compared to younger adults.

How to take it

Swallow the tablets whole with a full glass of 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

APO-TRAMADOL SR may be taken, before, with, or after food.

How long to take it

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 APO-TRAMADOL SR, and the cause of your pain.

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

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.

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 (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 APO-TRAMADOL SR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using APO-TRAMADOL SR

Things you must do

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

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 APO-TRAMADOL 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 must not do

Do not take APO-TRAMADOL SR 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.

Things to be careful of

Be careful driving or operating machinery until you know how APO-TRAMADOL SR affects you.

This medicine 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 APO-TRAMADOL SR.

Side effects

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

This medicine 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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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:

- dizziness
- sedation, fatigue or lack of energy
- headache
- constipation
- nausea, vomiting
- sweating
- dry mouth

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- indigestion
- changes in appetite
- skin reactions
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor
- seizures
- respiratory depression
- improvement or changes in mood or behaviour
- confusion, delirium, anxiety
- change in sensations such as pricking or tingling
- sleep disturbance
- changes in activity, co-ordination or speech
- blurred vision or changes to the eye
- slow or fast heart beat
- difficulty in passing urine
- Serotonin Syndrome: signs of this 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.

The above list includes common side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- convulsions

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

When used as prescribed by your doctor, addiction to APO-TRAMADOL SR is very unlikely.

If you are taking APO-TRAMADOL SR 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 APO-TRAMADOL SR only as directed by your doctor.

After using APO-TRAMADOL 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 tablets in a cool dry place where the temperature stays below 25°C.

Do not store APO-TRAMADOL 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

APO-Tramadol SR 100 mg – off-white, round biconvex tablet

APO-Tramadol SR 150 mg – off-white, capsule shaped tablet

APO-Tramadol SR 200 mg – off-white, capsule shaped tablet

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

Ingredients

Active ingredient:

- Tramadol hydrochloride

Inactive ingredients:

- Calcium hydrogen phosphate dihydrate
- Hyprolose
- Colloidal anhydrous silica
- Magnesium stearate

Distributor

APO-TRAMADOL SR is distributed in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue Macquarie Park
NSW 2113

This leaflet was prepared in April 2020.

APO-Tramadol SR 100 mg: AUST R
154393

APO-Tramadol SR 150 mg: AUST R
154394

APO-Tramadol SR 200 mg: AUST R
154395

APO-TRAMADOL SR_cmi\0320/21