

APO-TRAMADOL SR

Tramadol hydrochloride

Consumer Medicine Information

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

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 replace talking to your doctor or pharmacist.

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

All medicines have risks and benefits. If you have any concerns or want more information about your medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine 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

Your doctor may have prescribed APO-Tramadol SR for another reason. Ask your doctor why this medicine has been prescribed for you.

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

APO-TRAMADOL SR is available only on a doctor's prescription.

Before you use this medicine

When you must not take it

Do not take this medicine if:

- you have an allergy to any of the ingredients (see Product description below)
- you have an allergy to any other medicines known as opioid analgesics, e.g. 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

Do not take APO-Tramadol SR if the packaging is torn or shows signs of tampering

Do not take APO-Tramadol SR if any tablets look damaged or discoloured

Do not take APO-Tramadol SR if it is after the expiry date which is Do not give APO-Tramadol SR to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Before you start to take it

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

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

- any lung or breathing problems
- fits or convulsions, or take medicines for epilepsy

- any disorder of the kidney, liver or pancreas
- any stomach problems or severe headaches or have had a head injury

Tell your doctor if you have, or have had, any drug or alcohol

dependence

Tell your doctor if you have galactose intolerance, or lactase deficiency or glucose- galactose malabsorption

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

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

Tell your doctor if you are driving or operating machinery. APO-TRAMADOL SR may make you drowsy or dizzy. Ask your doctor for advice about whether it is safe for you to drive or operate machinery while taking APO-TRAMADOL SR.

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

APO-TRAMADOL SR is not recommended for children under 12 years.

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

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 this one 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, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin nor adrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- some antibiotics

These medicines may be affected by this medicine 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

APO-TRAMADOL SR 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 the analgesic quite quickly. Side-effects may then occur.

How much to take

The recommended dosage of APO-TRAMADOL SR is either:

- two APO-TRAMADOL SR 50 tablets twice a day (morning and evening)

OR

- 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 eight of the 50 mg tablets per day.

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 long to take it

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 take too much (overdose)

In the event of overdose, you should contact your nearest Poisons Information Centre (tel: 131 126), doctor or hospital emergency department immediately. Overdosage with APO-TRAMADOL SR may result in decrease in breathing and fits or convulsions.

While you are using this medicine

Things you must do

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

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 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.

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

Your doctor may do some tests (add specific tests as per PI) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

- take only as your doctor has told you.
- if you feel that you do not need as much APO-TRAMADOL SR 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 APO-TRAMADOL SR unless your doctor advises you to.
- Do not give your medicine to anyone else, even if they have similar symptoms to you. Your medicine is for your use only, it may harm other people.

Side effects

Tell your doctor or pharmacist as All medicines can cause unwanted effects, and some side-effects have been reported with APO-TRAMADOL SR. Side-effects reported with APO-TRAMADOL SR are usually minor and temporary, but some may be serious.

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

- dizziness
- sedation, fatigue
- 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 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, 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 serious 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
- 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.

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.

Can APO-TRAMADOL SR be addictive?

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.

Storage and Disposal

Storage

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

Keep it where children cannot reach it.

Keep away from direct sunlight.

Do not use APO-TRAMADOL SR after the use-by-date printed on the label of the pack.

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
AUST R 154393

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

154394

APO-Tramadol SR 200 mg - off-white, capsule shaped tablet
AUST R 154395

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

Ingredients

Active ingredient:

- Tramadol hydrochloride

Inactive ingredients:

- Calcium hydrogen phosphate
- Hyprolose
- Silica - colloidal anhydrous
- Magnesium stearate

Supplier

This medicine is supplied in Australia by:

Southern Cross Pharma Pty Ltd

Suite 5/118 Church St

Hawthorn VIC 3122

This leaflet was prepared in July 2018