APO-TRAMADOL SR

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 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.

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

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 APO-Tramadol SR

Do not use APO-TRAMADOL SR 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, 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

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

You must tell your doctor if:

- you are known to be sensitive to opioids
- you have any health problems including:
  - any lung or breathing problems
  - fits or convulsions, or take medicines for 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.
- you are pregnant or intend to become pregnant. APO-Tramadol SR is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using APO-Tramadol SR during pregnancy.
- you are breast feeding or plan to breast feed. APO-TRAMADOL SR is not recommended for use during breast feeding. Talk to your doctor about the risks and benefits of using APO-TRAMADOL SR during pregnancy.
- 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 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 APO-TRAMADOL SR.

These include:

- carbamazepine (eg. Tegretol®)
- coumarin derivatives (eg. 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), serotoninnoradrenaline reuptake inhibitors (SNRI's), tricyclic antidepressants, quinidine, phenothiazines or antipsychotics
- some antibiotics.

These medicines may be affected by APO-TRAMADOL SR, 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 APO-TRAMADOL SR.

How to take APO-TRAMADOL SR

APO-TRAMADOL SR tablets should be swallowed whole with water. They maybe 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 APOTRAMADOL 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.

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.

How long to take it

This differs between individuals depending on how severe your pain is, how you respond to APOTRAMADOL SR, and the cause of your pain. Ask your doctor for advice on how long you need to take APO-TRAMADOL SR tablets.

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.

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.

Side effects of APO-TRAMADOL

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.

The most common side-effects of APO-TRAMADOL SR 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 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.

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.

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.

After using APO-Tramadol SR

Storage

Keep APO-TRAMADOL SR 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 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 APO-Tramadol SR 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
- Hyprolose
- Silica – colloidal anhydrous
- Magnesium stearate

Supplier

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

Date of Preparation:

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AUST R Number

APO-Tramadol SR 100 mg: AUST R 154393

APO-Tramadol SR 150 mg: AUST R 154394

APO-Tramadol SR 200 mg: AUST R 154395