

APO-Tramadol

Contains the active ingredient tramadol hydrochloride

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about tramadol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,

- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Tramadol. It contains the active ingredient tramadol hydrochloride.

It is used to treat:

- moderate to severe pain

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

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

Tramadol is not normally addictive, although some cases have been reported.

Use in children

This medicine should not be used in children. The safety and effectiveness of this medicine in children have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You have or have had any of the following:
 - epilepsy which is not well controlled
 - known sensitivity to opioids (such as morphine or codeine).
- You are taking a class of medicine known as 'monoamine oxidase inhibitors' (MAOIs) (often taken for depression), or you have taken such a medicine within the last 14 days.
- You have recently taken large amounts of alcohol, hypnotics (often used to treat insomnia), analgesics (painkillers), opioids (also often used to treat pain), or psychotropic drugs (affect brain function)
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

- **You are hypersensitive to, or have had an allergic reaction to, tramadol or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - lung or breathing problems
 - serious head injury, shock or reduced levels of consciousness
 - diseases of the kidney or liver

- acute abdominal or stomach problems
 - seizures, fits or convulsions/epilepsy
 - dependence on opioid medications (such as morphine or codeine).
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with tramadol. These include:

- certain medicines used to treat depression, sleeplessness or mental conditions (such as MAOIs, selective serotonin reuptake inhibitors (SSRIs), tricyclic anti-depressants, phenothiazines or anti-psychotics)

- CNS depressants (such as alcohol, opioids, tranquilisers or sedative hypnotics)
- carbamazepine, a medicine mainly used to treat epilepsy
- coumarin derivatives (such as warfarin)
- ondansetron, a medicine used to treat nausea and vomiting.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with tramadol.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

For moderate pain:

The usual adult dose is one or two capsules taken two or three times daily.

One capsule (50 mg) may be enough for the first dose.

For moderate to severe pain:

The usual adult dose is one or two capsules, every four to six hours.

Two capsules (100 mg) are usually required for the first dose.

Do not take more than eight capsules (400 mg) per day.

If you are over 75 years of age, do not take more than six capsules (300 mg) per day, as you may require a lower daily dose.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

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

They may be different to the information contained in this leaflet.

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

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours

- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking tramadol or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following.

Mostly, these are mild:

- dizziness
- drowsiness
- dry mouth

- headache
- physical weakness or loss of strength
- fatigue
- nausea or vomiting
- constipation
- indigestion and stomach pain
- flatulence.

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

These may be serious side effects. You may need medical attention.

- itchy skin/rash
- sudden onset of low blood pressure; collapse
- fast heart beat
- hot flushes
- tremors/shakes
- increase in blood pressure
- slow heart beat
- shortness of breath

- changes in appetite
- changes in mood
- sleep disturbances
- muscle weakness
- difficulty in breathing
- difficulty or pain in passing urine
- blurred vision
- problems with speech
- dilated pupils.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- Serotonin Syndrome: symptoms of which may vary and are not specific, they may include: fever, sweating, confusion, agitation, diarrhoea, muscle twitching, difficulty with walking and balance
- hallucinations
- seizures

Other side effects not listed above may occur in some patients.

Some patients may experience withdrawal symptoms after they stop taking this medicine, such as agitation, trouble sleeping or tremors. Tell your doctor if you experience withdrawal symptoms.

Allergic reactions

If you think you are having an allergic reaction to tramadol, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

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

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Tramadol looks like

The capsules have a green cap and yellow body and are filled with a homogeneous white to off-white powder.

They are available in blister packs of 20 capsules.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 50 mg of tramadol hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Sodium starch glycollate
- Colloidal anhydrous silica
- Magnesium stearate
- Iron oxide yellow (E172)
- Indigo carmine aluminium lake (E132)
- Sodium lauryl sulfate
- Methyl hydroxybenzoate (E218)
- Propyl hydroxybenzoate (E216)
- Gelatin

This medicine contains hydroxybenzoates and sulfites. It is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Tramadol 50mg capsules (blisters): AUST R 158470.

Sponsor

Apotex Pty Ltd

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Distributor

This leaflet was last updated in:

June 2019.