

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

This leaflet answers some common questions about this medicine. 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 this medicine 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 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 an allergy to:

- any medicine containing

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 had any of the following medical conditions:

- epilepsy which is not well controlled
- a known sensitivity to opioids (such as morphine or codeine).

Do not take this medicine if 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.

Do not take this medicine if you have recently taken:

- large amounts of alcohol

- hypnotics (often used to treat insomnia)
- analgesics or opioids (used to treat pain)
- psychotropic drugs (medicines that may affect brain function).

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 have or have had any of the following medical conditions:

- lung or breathing problems
- sleep-related breathing disorders
- 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 drugs, such as opioid medications (e.g. morphine or codeine), or alcohol.

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

Do not take this medicine whilst pregnant or breastfeeding until you and your doctor have discussed the risks and benefits involved.

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

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 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.

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

How to take this medicine

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

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

Swallow the capsules with a full glass of water.

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 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 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

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 or start to breastfeed 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 your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine 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.

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

If you are taking tramadol 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.

Things to be careful of

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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
- 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:

- itchy skin/rash
- sudden onset of low blood pressure; collapse
- fast, slow or irregular heartbeat
- hot flushes
- tremors/shakes
- increase in blood pressure
- 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.

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:

- Serotonin Syndrome: symptoms of which may include fever, sweating, confusion, agitation, diarrhoea, muscle twitching, difficulty with walking and balance
- hallucinations
- seizures
- symptoms of an allergic reaction including 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

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 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.

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 windowsill 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.

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Macquarie Park NSW 2113

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This leaflet was last updated in July 2020.

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. AUST R 158470.

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 free from gluten, lactose, sucrose, tartrazine and other azo dyes.

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