

APO-TRAMADOL

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking APO-TRAMADOL, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before taking this medicine.

1. Why am I taking APO-TRAMADOL?

APO-TRAMADOL contains the active ingredient tramadol hydrochloride. APO-TRAMADOL is taken to relieve severe pain. For more information, see Section [1. Why am I taking APO-TRAMADOL?](#) in the full CMI.

2. What should I know before I take APO-TRAMADOL?

Do not take if you have ever had an allergic reaction to tramadol hydrochloride, any other opioid or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take APO-TRAMADOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-TRAMADOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take APO-TRAMADOL?

- Your doctor will tell you how much APO-TRAMADOL you should take. This will depend on your condition and whether you are taking other medicines.
- Patients over 75 years of age may require a lower daily dose.
- Swallow the capsules whole with a full glass of water.

More instructions can be found in Section [4. How do I take APO-TRAMADOL?](#) in the full CMI.

5. What should I know while taking APO-TRAMADOL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking APO-TRAMADOL.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking APO-TRAMADOL. It may affect other medicines used during surgery.• If you become pregnant or start to breastfeed while taking APO-TRAMADOL, tell your doctor immediately.• If your pain lessens or gets worse, consult your doctor.• If you are about to have any blood tests, tell your doctor that you are taking APO-TRAMADOL. It may affect the results of some tests.
Things you should not do	<ul style="list-style-type: none">• Do not take APO-TRAMADOL to treat any other complaints unless your doctor tells you to.• Do not give APO-TRAMADOL to anyone else, even if they have the same condition as you.• Do not stop taking APO-TRAMADOL or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how APO-TRAMADOL affects you.• APO-TRAMADOL may cause dizziness, light-headedness, tiredness or drowsiness in some people.
Drinking alcohol	<ul style="list-style-type: none">• You must not drink alcohol while taking APO-TRAMADOL.• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep capsules in the pack until it is time to take them. If you take the capsules out of the pack, they may not keep well. Store in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking APO-TRAMADOL?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects are dizziness, sedation, fatigue, drowsiness, dry mouth, headache, physical weakness or loss of strength, fatigue, nausea or vomiting, constipation, indigestion and stomach pain, flatulence and sweating.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Limitations of use:**

APO-TRAMADOL should only be taken when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

APO-TRAMADOL poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

APO-TRAMADOL can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting APO-TRAMADOL and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while taking APO-TRAMADOL

Taking APO-TRAMADOL with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking APO-TRAMADOL.

APO-TRAMADOL

Active ingredient: *tramadol hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-TRAMADOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-TRAMADOL.**

Where to find information in this leaflet:

- [1. Why am I taking APO-TRAMADOL?](#)
- [2. What should I know before I take APO-TRAMADOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APO-TRAMADOL?](#)
- [5. What should I know while taking APO-TRAMADOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking APO-TRAMADOL?

APO-TRAMADOL contains the active ingredient tramadol hydrochloride. Tramadol hydrochloride belongs to the group of medicines called opioid analgesics (pain relievers).

APO-TRAMADOL is used to relieve severe pain.

APO-TRAMADOL is not normally addictive. However, rarely, addiction to tramadol hydrochloride has been reported.

Tramadol hydrochloride is for use in adults and children over 12 years of age. APO-TRAMADOL should not be used in children under 12 years of age or following the removal

of tonsils and/or adenoids in people between 12 and 18 years of age.

2. What should I know before I take APO-TRAMADOL?

Warnings

Addiction

You can become addicted to APO-TRAMADOL even if you take it exactly as prescribed. APO-TRAMADOL may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking APO-TRAMADOL. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking APO-TRAMADOL suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to APO-TRAMADOL may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking APO-TRAMADOL for as long as your doctor tells you. If you stop taking APO-TRAMADOL suddenly, your pain may worsen and you may experience some or all the following withdrawal symptoms:

- Nervousness, restlessness, agitation, trouble sleeping or anxiety.
- Body aches, weakness or stomach cramps.

- Loss of appetite, nausea, vomiting or diarrhoea.
- Increased heart rate, breathing rate or pupil size.
- Watery eyes, runny nose, chills or yawning.
- Increased sweating.

Very rarely, some patients have experienced the following withdrawal reactions:

- Panic attacks.
- Severe anxiety.
- Hallucinations.
- Tingling or numbness (pins and needles).
- Ringing in your ears.
- Confusion, delusions or paranoia.

APO-TRAMADOL given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you are not sure whether you should start taking APO-TRAMADOL, talk to your doctor.

Do not take APO-TRAMADOL if:

- you are allergic to tramadol hydrochloride, or any other opioids such as morphine or codeine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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.
- you have taken large amounts of alcohol or other substances which can affect your level of consciousness. Some examples of these include hypnotics (often used to treat insomnia), analgesics or opioids (used to treat pain), psychotropic drugs (medicines that may affect mood and emotions).
- you have epilepsy which is not well controlled.
- you have respiratory disease or slow or shallow breathing.
- you are taking medicine for depression containing a “monoamine oxidase inhibitor” also known as MAOI, or you have taken such a medicine within the last two weeks.
- you are younger than 12 years old or if you are between 12 and 18 years of age and are recovering from an operation to remove your tonsils and/or adenoids.

You must tell your doctor if:

- you have known allergy to APO-TRAMADOL or any of the ingredients listed at the end of this leaflet.
- you are known to be sensitive to opioids.
- you drink alcohol.
- you have or ever had any other health problems including:
 - any lung or breathing problems
 - sleep-related breathing disorders

- any conditions that may affect how you kidney or liver work
- any stomach problems
- a severe headache or feeling sick due to a head injury
- any fits or convulsions or take medicine for epilepsy.

- you are pregnant or intend to become pregnant. APO-TRAMADOL is not recommended during pregnancy. APO-TRAMADOL can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using APO-TRAMADOL during pregnancy.
- you are breastfeeding or plan to breastfeed. APO-TRAMADOL is not recommended for use during breastfeeding. Talk to your doctor about the risks and benefits of taking APO-TRAMADOL when breastfeeding.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

APO-TRAMADOL is not recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

APO-TRAMADOL is not recommended for use during breastfeeding. Your doctor can discuss with you the risks and benefits involved.

What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APO-TRAMADOL and affect how it works. 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, tranquillisers or sedative hypnotics).
- Carbamazepine, a medicine mainly used to treat epilepsy.
- Coumarin derivatives (such as warfarin).
- Medicine for irregular or rapid heartbeat.

- Ondansetron, a medicine used to treat nausea and vomiting.
- Some antibiotics.
- A group of medicines called anticholinergics. These medicines can be used to treat a wide range of medical conditions including asthma, a respiratory condition called chronic obstructive pulmonary disorder (COPD), Parkinson's Disease, cardiovascular disease, urinary incontinence (loss of bladder control), psychiatric disorders including schizophrenia, anxiety, depression, allergies and travel sickness/nausea.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-TRAMADOL.

3. How do I take APO-TRAMADOL?

How much to take

Your doctor will tell you how many APO-TRAMADOL capsules you should take. This will depend on your condition and whether you are taking any other medicines.

An initial dose of one APO-TRAMADOL capsule may provide sufficient pain relief, followed by one or two capsules two or three times a day as required.

For more severe pain, two APO-TRAMADOL capsules are usually required for the first dose, followed by one or two capsules every four to six hours as required.

Patients over 75 years of age may require a lower daily dose.

Do not take more than eight APO-TRAMADOL capsules per day.

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

These directions may differ from the information in this leaflet.

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

How to take APO-TRAMADOL

Swallow the capsules with a full glass of water.

When to take APO-TRAMADOL

Take APO-TRAMADOL at the same time each day.

Taking APO-TRAMADOL 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 APO-TRAMADOL before, with or after food.

How long to take APO-TRAMADOL

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

Continue taking APO-TRAMADOL for as long as your doctor tells you.

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

If you forget to use APO-TRAMADOL

If you forget to take a dose, you can take it as soon as you remember. The next dose should be taken after four or six hours, or as prescribed by your doctor.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect. 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 APO-TRAMADOL

If you think that you have taken too much APO-TRAMADOL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If someone takes an overdose, they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing.
- Drowsiness, dizziness or unconsciousness.
- Slow or weak heartbeat.
- Nausea or vomiting.
- Convulsions or fits.

When seeking medical attention, take this leaflet and remaining medicine with you to show it to the doctor. Also tell them about any other medicines or alcohol which have been taken.

4. What should I know while taking APO-TRAMADOL?

Things you should do

If you are about to start 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 your pain is not as severe and you feel that you do not need as many APO-TRAMADOL capsules as your doctor prescribed, consult your doctor.

Tell your doctor if your pain has not helped or gets worse. Do not take increased amounts or extra doses without checking with your doctor.

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 should not do

Do not take APO-TRAMADOL to treat any other complaints unless your doctor tells you to.

Do not give APO-TRAMADOL to anyone else, even if they have the same condition as you.

Do not stop taking APO-TRAMADOL or change the dosage without checking with your doctor.

If you are taking APO-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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-TRAMADOL affects you.

APO-TRAMADOL may cause dizziness, lightheadedness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

You must not drink alcohol while taking APO-TRAMADOL.

Looking after your medicine

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

Keep your capsules in a place where the temperature stays below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

5. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Dizziness. • Sedation, fatigue. • Drowsiness. • Dry mouth. • Headache. • Physical weakness or loss of strength. • Fatigue. • Nausea or vomiting. • Constipation. • Indigestion and stomach pain. • Flatulence. • Sweating. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Indigestion. • Skin reactions. • Hiccups. • Sudden onset of low blood pressure, collapse. • Fast, slow or irregular heartbeat. • Hot flushes. • Tremors/shakes. • Seizures. • Increase in blood pressure. • Shortness of breath. • Respiratory depression. • 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. • Confusion. • Serotonin Syndrome: signs of this vary and are not specific: they may include sweating, agitation, muscle twitching, tremor, spontaneous muscle contraction, high body temperature. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
for example, the SSRI antidepressants. <ul style="list-style-type: none"> • Low blood glucose (hypoglycaemia). 	

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.</p>

Talk to your doctor if you experience any of the following symptoms while taking this medicine.

Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops.

Severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.

APO-TRAMADOL can cause sleep related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.

Extreme fatigue, lack of appetite, weight loss, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels).

Adrenal insufficiency is caused by failure of the adrenal glands to produce enough or any of the hormones cortisol and aldosterone.

If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

6. Product details

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

What APO-TRAMADOL contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • Tramadol hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Microcrystalline cellulose • Sodium starch glycollate • Colloidal anhydrous silica • Magnesium stearate • Iron oxide yellow • Indigo carmine aluminium lake • Sodium lauryl sulfate • Methyl hydroxybenzoate • Propyl hydroxybenzoate • Gelatin • Titanium dioxide
Potential allergens	<ul style="list-style-type: none"> • APO-TRAMADOL contains hydroxybenzoates and sulfites. • APO-TRAMADOL may contain trace amounts of phenylalanine.

APO-TRAMADOL does not contain gluten, lactose, sucrose, tartrazine and other azo dyes

Do not take APO-TRAMADOL if you are allergic to any of these ingredients.

What APO-TRAMADOL looks like

APO-TRAMADOL 50 mg Capsules

Hard gelatin capsules having green cap and yellow body filled with a homogeneous white to off-white powder.

APO-TRAMADOL is available in blister packs of 6, 8, 10 and 20 capsules*.

*Not all pack sizes may be available.

AUST R 158470.

Who distributes APO-TRAMADOL

Arrotex Pharmaceuticals Pty Ltd

15 - 17 Chapel Street

Cremorne VIC 3121

Web: <https://arrotex.com.au>

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