

# APO-Tramadol

Contains the active ingredient tramadol hydrochloride

## Consumer Medicine Information

### WARNING

#### Limitations of use

TRAMADOL should only be used 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

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

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 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 using TRAMADOL

Using 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 using TRAMADOL.

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 relieve:

- Severe pain, and belongs to a group of medicines called opioid analgesics (pain relievers).

**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

**Tramadol is used in adults and children over 12 years of age.**

This medicine should not be used in children under 12 years of age or following the removal of tonsils and/or adenoids in people under 18.

### Before you take this medicine

#### When you must not take it

**Do not take this medicine if you have an allergy to:**

- Tramadol or any of the ingredients listed at the end of this leaflet.
- Any other medicines known as opioid analgesics, e.g. morphine or codeine

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:**

- respiratory disease or slow or shallow breathing

- epilepsy which is not well controlled

**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 if you are younger than 12 years old or if you are between 12 – 18 years of age and are recovering from an operation to remove your tonsils and/or adenoids.**

**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 you take this medicine after the expiry date has passed, it may not work as well.

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.**

#### Addiction

You can become addicted to tramadol even if you take it exactly as prescribed. 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 tramadol. Taking it may result in physical dependence.

Physical dependence means that you may experience withdrawal symptoms if you stop taking tramadol suddenly, so it is important to take it exactly as directed by your doctor.

#### Tolerance

Tolerance to 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 your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of 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.

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 this medicine, talk to your doctor.**

*Before you start to take it*

**Tell your doctor if you have allergies to tramadol, or any of the ingredients listed at the end of this leaflet, or 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.
- You are known to be sensitive to opioids
- You drink alcohol
- A severe headache or feel sick due to a head injury

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

This medicine can pass to your unborn baby when you are pregnant.

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)
- medicine for irregular or rapid heart beat
- ondansetron, a medicine used to treat nausea and vomiting.
- Some antibiotics

These medicines may be affected by tramadol, or may affect how well it works. 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.**

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### **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.

An initial dose of one 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 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 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 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*

**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 this medicine.**

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

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

**Carefully follow all directions given to you by your doctor and the pharmacist.**

#### *If you forget to take it*

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 (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.**

**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

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

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

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### **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 your pain is not as severe and you feel that you do not need as much tramadol capsules as your doctor prescribed, consult your doctor.

Tell your doctor if your pain is 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 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.**

This medicine may cause dizziness, light-headedness, 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.

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### **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
- Sedation, fatigue
- drowsiness
- dry mouth
- headache
- physical weakness or loss of strength
- fatigue
- nausea or vomiting
- constipation
- indigestion and stomach pain
- flatulence.
- sweating

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

- 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, for example, the SSRI antidepressants.
- Low blood glucose (hypoglycaemia)

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Extreme fatigue, lack of appetite, 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 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.**

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## 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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## 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 6, 8, 10 and 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
- Titanium dioxide

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

May contain trace amounts of phenylalanine.

### *Sponsor*

Arrotex Pharmaceuticals Pty Ltd  
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Web: <https://arrotex.com.au>

This leaflet was last updated in August 2023.