

APO-Tramadol/Paracetamol 37.5/325 Tablets

Tramadol hydrochloride and paracetamol

Consumer Medicine Information

WARNINGS

Limitations of use

Tramadol/Paracetamol tablets 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/Paracetamol tablets 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/Paracetamol tablets 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/Paracetamol tablets 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/Paracetamol tablets

Using Tramadol/Paracetamol tablets 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/Paracetamol tablets.

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 using 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 want to read it again.

What this medicine is used for

This medicine contains the active ingredients, tramadol and paracetamol. Both ingredients belong to a group of medicines called analgesics. This combination acts to relieve moderate pain.

Tramadol/paracetamol is indicated for the short-term management of severe pain for which other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain.

There is evidence that the tramadol component of this medicine can be addictive.

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.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you take this medicine

When you must not take it

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

- tramadol
- paracetamol
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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
- drop of blood pressure and fainting

Do not take this medicine if you have or have had any of the following medical conditions:

- severe liver disorder
- uncontrolled epilepsy

Do not take this medicine if you are pregnant, plan to become pregnant or are breastfeeding. Tramadol should not be taken during pregnancy or breastfeeding.

Tramadol may affect your developing baby if you take it during pregnancy. It may also pass into breast milk and affect your baby.

Do not take this medicine if you have consumed a lot of alcohol.

Do not take this medicine if you have taken more than the recommended amount of:

- sleeping tablets
- other pain-relieving medications that your doctor has prescribed or that you have bought from a pharmacy, supermarket or health food shop
- psychotropic medications (medicines that affect mood and emotions)

Do not take this medicine if you are taking or have taken any medicine called a monoamine oxidase inhibitor within the last 14 days.

Do not take this medicine if you weigh less than 37.5 kg.

Do not give this medicine to children of 12 years or under.

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 take other medicines containing paracetamol or tramadol hydrochloride.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- liver or bile ducts problems, liver disease or yellowing of eyes and/or skin (jaundice)
- kidney problems
- severe breathing difficulties, asthma or severe lung problems
- epilepsy, fits or seizures

- recent head injury, shock or severe headaches associated with vomiting
- drug dependence
- taking other medicines to treat pain that contain buprenorphine or pentazocine
- dehydration
- eating disorders (e.g. anorexia or bulimia)
- body weight less than 37.5 kg
- wasting syndrome including unexplained weight loss, fatigue, weakness and loss of appetite
- malnutrition (low reserves of glutathione)
- sleep-related breathing disorders including central sleep apnoea and sleep-related hypoxemia (low levels of oxygen)

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

- Your doctor can discuss with you the risks and benefits involved.
- This medicine contains tramadol hydrochloride which should not be taken during pregnancy and breast feeding.
- If you become pregnant during treatment, consult your doctor before taking any further tablet.

Tell your doctor if you drink alcohol.

Tell your doctor or dentist that you are taking this medicine if you plan to have any surgery or procedure that requires an anaesthetic.

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 if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

The following medicines must not be taken at the same time as this medicine:

- any other medicines containing tramadol or paracetamol
- monoamine oxidase inhibitors (MAOIs), used to treat depression (e.g. phenelzine, tranylcypromine or moclobemide)
- carbamazepine, used to treat epilepsy or some types of pain
- buprenorphine or pentazocine, used to treat pain

The risk of side effects increases, if you taking:

- medicines to treat depression, anxiety, obsessive-compulsive disorder or mood disorders (such as SSRIs). You may

experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C.

- tranquilizers, sleeping pills or other pain relievers such as morphine and codeine (also as cough medicine). You may feel drowsy or feel faint. If this happens, tell your doctor.
- baclofen, used as a muscle relaxant
- some medicines used to lower blood pressure
- some medicines to treat allergies (antihistamines, especially if they are sedating)
- triptans, used to treat migraine (e.g. sumatriptan). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- medicines that may cause convulsions (fits) (e.g. certain antidepressants, antipsychotics or bupropion). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.
- warfarin or other medicines that thin the blood (e.g. phenprocoumon). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effect of Zaldiar may be altered if you also take:

- metoclopramide, domperidone or ondansetron, used to treat nausea and vomiting
- cholestyramine, used to reduce cholesterol in the blood
- busulfan, a cancer therapy
- medicines used to treat infections (e.g. ketoconazole or erythromycin)

These medicines may be affected by tramadol/paracetamol or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will tell you whether Zaldiar is suitable for you.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

Other medicines not listed above may also interact with tramadol hydrochloride or paracetamol.

How to take this medicine

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

They may differ to the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much of this medicine you should take. The dosage should be adjusted to the intensity of your pain.

In general, the lowest pain-relieving dose should be taken.

The usual starting dose for adults and adolescents over 12 years is 2 tablets.

Additional tablets can be taken as recommended by your doctor. The shortest time between doses must be at least 6 hours.

Do not take more than 8 tablets per day.

If you weigh between 37.5 kg and 50 kg, you should not take more than 6 tablets daily.

Your doctor may reduce the maximum number of tablets you can take each day if you:

- are over 75 years of age
- have mild to moderate liver problems
- weigh between 37.5 kg and 50 kg
- have kidney problems

Your doctor will check how well this medicine is working at regular intervals.

How to take it

Swallow the tablets with a full glass of water.

Do not break or chew the tablet.

If you forget to take Tramadol/Paracetamol

The pain is likely to return.

Take it as soon as you remember, and then go back to taking it as before.

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

If you are not sure what to do, ask your doctor or pharmacist.

When to take it

It does not matter if you take this medicine with or without food.

How long to take it for

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.

Tramadol/paracetamol given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you take too much

Tramadol/Paracetamol (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Tramadol/ paracetamol that was prescribed for you. 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

If you think you or someone else may have used too much Tramadol/ Paracetamol 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.

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.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking this medicine.

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

If you become pregnant or start breastfeeding while taking this medicine, tell your doctor immediately.

Tell your doctor if you are going to have surgery, an anaesthetic or are going into hospital.

Tell your doctor if you feel the dose you are taking is too strong or too weak.

If the dose is too strong, you may feel very drowsy or have difficulty breathing. If the dose is too weak, you may continue to feel some pain between doses.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not change the dosage without first checking with your doctor.

If you have been taking this medicine for a while, do not stop treatment abruptly as this may make you feel unwell.

Speak to your doctor if you have any concerns about taking this medicine long-term.

Do not consume alcohol while taking this medicine.

Things to be careful of

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

It may cause dizziness and drowsiness in some people. Make sure you know how you react to this medicine before you drive a car, or do anything else that could be dangerous if you are dizzy.

This effect may be made worse by drinking alcohol or some other medicines that act on the central nervous system.

Addiction

You can become addicted to Tramadol/paracetamol even if you take it exactly as prescribed. Tramadol/paracetamol 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/ paracetamol. Taking it may result in physical dependence. Physical dependence means that you

may experience withdrawal symptoms if you stop taking Tramadol/ paracetamol suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Tramadol/paracetamol may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Side effects

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

This medicine helps most people with pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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 if you notice any of the following side effects:

Very common:

- nausea
- dizziness
- drowsiness

Common:

- digestion problems, such as constipation, wind, diarrhoea, stomach pain or vomiting
- dry mouth
- itching
- sweating (hyperhidrosis)
- headache
- shaking
- confusion
- sleep disturbances
- mood change

Uncommon:

- increase in pulse or blood pressure, heart rate or rhythm disorders
- difficulty or pain on passing urine
- skin reactions (e.g. rash, hives)
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, involuntary muscle twitching
- depression, nightmares, hallucinations or memory lapses
- difficulty swallowing
- blood in stools
- shivering, hot flushes, pain in chest
- difficulty breathing

Rare:

- fits, difficulties in carrying out coordinated movements
- addiction
- blurred vision
- fainting (syncope)
- speech disorder
- delirium
- constriction of the pupil (miosis)
- excessive dilation of the pupils (mydriasis)

The following are side effects which have been reported by people using ONLY tramadol or ONLY paracetamol. Tell your doctor as soon as possible if you notice any of the following:

- feeling faint when getting up from a lying or sitting position

- slow heart rate
- fainting
- changes in appetite
- muscle weakness
- slower or weaker breathing
- mood changes
- changes in activity
- changes in perception
- worsening of existing asthma

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

- decreased blood pressure
- fainting
- yellowing of the skin and/or eyes (jaundice)
- 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 (signs of an allergic reaction)

Some of the above could be a sign of an allergic reaction. You may need urgent medical attention or hospitalisation. Allergic reactions are rare.

In rare cases, taking strong pain killers may make you become dependent on them, making it hard to stop taking it.

On rare occasions, people who have been taking tramadol hydrochloride for some time may feel unwell if they stop treatment abruptly. Symptoms may include:

- feeling agitated, anxious, nervous or shaky

Very few people may also get:

- panic attacks
- hallucinations
- unusual perceptions, such as itching, tingling and numbness, noise in the ears (tinnitus).

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After taking this medicine

Storage

Keep your tablets in the blister pack until you take them.

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

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

Do not refrigerate or

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 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.

Product description

What it looks like

Yellow, capsule-shaped, biconvex, film-coated tablet. Engraved "APO" on one side and "37.5 - 325" on the other side.

Available in blister packs of 6, 8, 10, 20 or 50 tablets. AUST R 280699.

Ingredients

Each tablet contains 37.5 mg of tramadol hydrochloride and 325 mg of paracetamol as the active ingredients.

It also contains the following:

- povidone
- pregelatinised maize starch
- stearic acid
- microcrystalline cellulose
- croscarmellose sodium

Film coating:

- hypromellose
- hypolose
- macrogol 8000
- titanium dioxide
- iron oxide yellow

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

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