

APO-Tramadol/ Paracetamol 37.5/325 Tablets

Tramadol hydrochloride and paracetamol

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 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.

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.

Do not take this medicine if you are 12 years of age or under.

Safety and effectiveness in children younger than 12 years of age has 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:

- 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

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 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
- psychotropic medications (medicines that affect mood and emotions)

Do not take this medicine if you are taking or have taken monoamine oxidase inhibitors within the last 14 days

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:

- liver or bile ducts problems, liver disease or yellowing of eyes and/or skin (jaundice)
- kidney problems
- severe breathing difficulties, asthma, 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)
- low body weight less than 37.5 kg
- wasting syndrome including unexplained weight loss, fatigue, weakness and loss of appetite
- malnutrition (low reserves of glutathione)

Tell your doctor if you drink alcohol.

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

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. Tramadol may also pass into breast milk and affect your baby.

If you become pregnant during treatment, do not take this medicine 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 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, moclobemide)
- carbamazepine, used to treat epilepsy or some types of pain
- buprenorphine or pentazocine, used to treat pain

Some medicines and this one may interfere with each other. This includes:

- medicines to treat depression, anxiety, obsessive-compulsive disorder or mood disorders.
- triptans, used to treat migraine (e.g. sumatriptan)
- medicines that may cause convulsions (fits) (e.g. certain antidepressants, antipsychotics, bupropion)
- warfarin or other medicines that thin the blood
- metoclopramide, domperidone or ondansetron, used to treat nausea and vomiting
- cholestyramine, used to reduce cholesterol
- busulfan, a cancer therapy
- medicines used to treat infections (e.g. ketoconazole, erythromycin)

These medicines may be affected by this medicine 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 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 box, 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 is 2 tablets taken every 6 hours as needed.

Do not take more than 8 tablets per day.

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

How to take it

Swallow the tablets with a full glass of water. Do not break or chew the tablet.

When to take it

It does not matter if you take this medicine with or without 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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. There is a risk of liver damage which may only show later. You may need urgent medical attention.

Symptoms of an overdose may include: constriction of the pupil, vomiting, pallor, anorexia, nausea, cardiovascular collapse, consciousness disorders up to coma, abdominal pain, convulsions and difficulty breathing.

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 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. Do not consume alcohol while taking this medicine.

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:

- nausea
- dizziness
- drowsiness
- digestion problems, such as constipation, wind, diarrhoea, stomach pain, vomiting
- dry mouth
- itching
- sweating (hyperhidrosis)
- headache
- shaking
- confusion
- sleep disturbances
- mood change
- 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, memory lapses
- difficulty swallowing
- blood in stools
- shivering, hot flushes, pain in chest
- 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)

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.

Storage and disposal

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 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 tells you to stop taking this medicine or after the expiry date has passed, ask your pharmacist what to do with any medicine left over.

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 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
- hypromellose
- 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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