

PACKAGE LEAFLET: Information for the patient

TRAMADOL

Oral drops, solution – 100 mg / ml

(Tramadol hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tramadol is and what it is used for
2. What you need to know before you take Tramadol
3. How to take Tramadol
4. Possible side effects
5. How to store Tramadol
6. Content of the pack and other information

1. WHAT TRAMADOL IS AND WHAT IT IS USED FOR

Tramadol contains the active substance tramadol hydrochloride, which belongs to the group of potent centrally acting analgesics.

Tramadol is a medicine for relieving moderate to severe pain. You should use it only if prescribed by a doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL

Do not take Tramadol:

- if you are allergic to tramadol hydrochloride or to any of the other ingredients of this medicine (listed in section 6);
- if you are taking monoamine oxidase inhibitors (MAO inhibitors) or have taken them in the past two weeks;
- if you have acute intoxication with alcohol, hypnotics, pain-relieving medicines or other medicines that act on the central nervous system;
- if you have acute respiratory depression;
- if you have conditions associated with raised intracranial pressure or head injury;
- if you have epilepsy not adequately controlled by treatment;
- if you have severe hepatic or renal impairment.

It should not be used in narcotic withdrawal treatment.

Children and adolescents

Tramadol drops are contraindicated in children below 1 year of age and they are not recommended for children below the age of 12 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol:

- if you are sensitive to opioid analgesics;
- if you are addiction-prone (alcoholism, tablet addiction and drug addiction);
- if you have periodic epileptic seizures;
- if you have kidney or liver problems;
- if you have serious breathing problems;
- if you have hypotension;
- if you have myasthenia gravis;
- if you have prostatic hypertrophy;
- if you have obstructive or inflammatory bowel disorders;
- if you have impaired consciousness.

It should be used with caution in patients with shock.

A reduced dose is recommended in elderly or debilitated patients, hypothyroidism, adrenocortical insufficiency.

Avoid abrupt withdrawal in long-term treatment.

Care should be taken if concomitant CNS depressant medicines are being administered or if the recommended dosage is significantly exceeded.

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be higher when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

In addition, tramadol may increase the seizure risk in patients taking other medicines that lower seizure threshold (see 'Other medicines and Tramadol').

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Please note that Tramadol oral drops may lead to physical and psychological addiction.

When Tramadol, oral drops, is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development).

In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with Tramadol oral drops should only be carried out for short periods and under strict medical supervision.

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

Please also inform your doctor if one of these problems occurs during treatment with Tramadol oral drops or if they applied to you in the past.

Children and adolescents

Use in children with breathing problems:

Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Sleep-related breathing disorders

Tramadol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) 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. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Tramadol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tramadol can affect the way in which some medicines work and vice versa. Such medicines include:

- central nervous system depressants (alcohol, anaesthetics, medicines for treating depressive disorders, medicines for treating mental disorders, sedatives, hypnotics);
- carbamazepine (an antiepileptic);
- MAO inhibitors (medicines for treating depression or Parkinson's disease);
- coumarin derivatives, (e.g. warfarin);
- mixed agonist / antagonist (e.g. buprenorphine, nalbuphine, pentazocine);
- cimetidine, metabolism of opioid analgesics inhibited by cimetidine (increased plasma concentration);
- ondansetron, effects of tramadol possibly antagonised by ondansetron.

The risk of side effects increases:

- if you are taking medicines which may cause convulsions (epileptic seizures), such as certain antidepressants or antipsychotics. The risk of having a seizure may increase if you take Tramadol at the same time. Your doctor will tell you whether Tramadol is suitable for you;

- if you are taking certain antidepressants, Tramadol may interact with these medicines and 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.

Tramadol with food, drink and alcohol

Do not drink alcohol during treatment with tramadol as the medicine increases the depressant action of alcohol on the central nervous system.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Safety of use during pregnancy has not been studied adequately, therefore this medicine should not be used in pregnant women. High doses or prolonged use during pregnancy may have harmful effects on the foetus or newborn baby.

Breastfeeding

Tramadol is excreted into breast milk. For this reason, you should not take Tramadol more than once during breastfeeding, or alternatively, if you take Tramadol more than once, you should stop breastfeeding.

Driving and using machines

The medicine has a potent effect on the psychophysical performance, especially when taken concomitantly with alcohol; you should therefore not use machines and drive motor vehicles during treatment.

Important information about some of the ingredients of Tramadol

Tramadol, oral drops, contains:

- sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This ingredient may be harmful to teeth during chronic use of this medicine.
- 150 mg propylene glycol / 1 ml solution.

3. HOW TO TAKE TRAMADOL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken.

Dosage guidelines:

Adults and children over 12 years of age:

The usual dose for adults and children aged 12 and over is 50 mg to 100 mg tramadol (20 to 40 drops), three to four times per day. The maximum allowed dose of Tramadol oral drops is generally 400 mg (160 drops) per day.

In children from 12 to 14 years, it is recommended to use the lowest dose.

For acute pain, a starting dose of 100 mg is generally required since the effect begins later than with other pain relievers.

For chronic pain, a starting dose of 50 mg is recommended.

It is recommended, when possible in case of chronic treatment, to slowly increase tramadol dosage to its final recommended dose (with increments every 2 to 3 days) in order to reduce the incidence of adverse events.

Use in children and adolescents

Tramadol drops are contraindicated in children below 1 year of age and they are not recommended for children below the age of 12 years.

Children 1 to 12 years of age:

Drops should be given at a dose of 1 mg/kg to 2 mg/kg body weight. The doses may be administered at 4-hour to 6-hour intervals. The size of doses and frequency of administration must be determined by the doctor.

Liver or kidney disease patients

Patients with severe liver and/or kidney insufficiency should not take Tramadol. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Elderly patients

In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval. You should discuss dosage adjustments with the doctor.

How and when should you take Tramadol oral drops?

Tramadol oral drops are for oral use.

Daily doses over 400 mg are not recommended, except in special clinic circumstances.

How long should you take Tramadol oral drops?

You should not take Tramadol oral drops for longer than necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to take Tramadol oral drops and at what dose.

If you have the impression that the effect of Tramadol oral drops is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tramadol than you should

If you have taken two prescribed doses of Tramadol by mistake, there will be no significant negative effect, but if you have taken a dose significantly higher than the recommended one, signs of intoxication may occur: pin-point pupils, vomiting, cardiovascular collapse, epileptic fits, disturbed consciousness up to coma (deep unconsciousness), and difficulty in breathing up

to cessation of breathing may occur. In this case contact your doctor immediately or go to the nearest hospital.

Treatment consists of general emergency measures. The respiratory tract should be kept open (aspiration!), respiration and circulation should be maintained depending on the symptoms. The antidote for respiratory depression is naloxone. In case of convulsions, intravenous diazepam should be used.

If you forget to take Tramadol

Do not take a double dose to make up for a forgotten dose.

You should continue treatment by taking the next scheduled dose in time.

If you stop taking Tramadol

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

Generally there will be no after-effects when treatment with Tramadol oral drops is stopped. However, on rare occasions, people who have been taking Tramadol oral drops for some time may feel unwell if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, severe anxiety hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of the own personality (depersonalization), change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely.

If you experience any of these complaints after having stopped taking Tramadol oral drops, please consult your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are most frequently related to high doses.

You **should see a doctor immediately** if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.

The **most common** side effects during treatment with Tramadol oral drops are nausea and dizziness, which occur in more than in 1 out of 10 patients.

Common: may affect up to 1 in 10 people

- vertigo, headache,
- constipation, vomiting, dry mouth, dyspepsia, abdominal pain,
- sleepiness,
- sweating,
- menopausal signs,
- fatigue, asthenia, malaise;

Uncommon: may affect up to 1 in 100 people

- diarrhoea, appetite disorders (anorexia),
- gastrointestinal disorders (pressure in the stomach, bloating), flatulence,
- hypersensitivity skin reactions (itching, skin rashes),
- urination disorders (urinary retention, frequent urination),
- cardiovascular collapse,
- toxic epidermal necrolysis and Stevens-Johnson syndrome, and cross reactivity with non-steroidal anti-inflammatory drugs;

Rare: may affect up to 1 in 1,000 people

- anxiety, confusion, mood changes (extremely cheerful mood or dysphoria), emotional instability, sleep disorders, cognitive disorders, sensory disorders and hallucinations,

- coordination disorders, muscle spasms, tingling (paraesthesia), tremor, epileptiform convulsions,
- accelerated heartbeat, unpleasant sensation of heart pounding (palpitations),
- fainting (syncope), increased blood pressure, a fall in blood pressure upon rising from a lying or sitting position,
- visual disturbances,
- menstrual disorders,
- serious allergic reaction that causes swelling of the face and throat (angioedema), dyspnea, bronchospasm, wheezing and anaphylaxis,
- increased muscle tone,
- micturition disorders (difficulty in passing urine, dysuria and urinary retention),
- muscle weakness,
- weight loss,
- dyspnea, respiratory depression, changes in appetite,
- dependence, suicidal ideation, drug abuse and addiction.

Very rare: may affect up to 1 in 10,000 people

- increase in liver enzyme values.

Not known: cannot be estimated from the available data

- hypoglycaemia,
- hyponatraemia,
- speech disorders,
- mydriasis,
- hiccups.

5. HOW TO STORE TRAMADOL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging.

Do not store above 25°C.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Tramadol contains

The active substance is tramadol hydrochloride.

1 ml of solution (40 drops) contains 100 mg tramadol hydrochloride.

The other ingredients of the oral drops are: glycerol, propylene glycol, sucrose, saccharine sodium, sodium cyclamate, potassium sorbate, peppermint oil, hydrochloric acid (pH adjuster), and purified water.

Contents of the pack

Box with a glass vial of 10 ml with a dropper.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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