Package leaflet: Information for the user

Tramadol 100mg/ml oral drops, solution

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

The name of your medicine is Tramadol 100mg/ml oral drops, solution. It will be referred to as "Tramadol oral drops" for ease of use hereafter.

What is in this leaflet

1. WHAT TRAMADOL ORAL DROPS ARE AND WHAT THEY ARE USED FOR

Tramadol (tramadol hydrochloride) – the active substance in Tramadol oral drops - is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.
Tramadol oral drops are used for the treatment of moderate to severe pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL ORAL DROPS

Do not take Tramadol oral drops:

• if you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6)
• in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)

• if you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days (see “Taking other medicines”)
• if you are an epileptic and your fits are not adequately controlled by treatment
• as a substitute in drug withdrawal.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Tramadol oral drops:
• if you think that you are addicted to other pain relievers (opioids)
• if you suffer from consciousness disorders (if you feel that you are going to faint)
• if you are in a state of shock (cold sweat may be a sign of this)
• if you suffer from increased pressure in the brain (possibly after a head injury or brain disease)
• if you have difficulty breathing
• if you have a tendency towards epilepsy or fits because the risk of a fit may increase
• if you suffer from a liver or kidney disease.

In such cases please consult your doctor before taking the medicine.
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 (400mg).
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 are 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.
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.

Other medicines and Tramadol oral drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Tramadol oral drops should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

Concomitant use of Tramadol oral drops and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Tramadol oral drops together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The pain-relieving effect of Tramadol oral drops may be reduced and the length of time it acts may be shortened, if you take medicines which contain

- **carbamazepine** (for epileptic fits)
- **pentazocine, nalbuphine or buprenorphine** (pain killers)
- **ondansetron** (prevents nausea).

Your doctor will tell you whether you should take Tramadol oral drops, and which dose. The risk of side effects increases

- if you take **tranquillizers, sleeping pills,** other **pain relievers** such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol oral drops. You may feel drowsier or feel that you might faint.

If this happens tell your doctor

- if you are taking medicines which may cause convulsions (fits), such as certain **antidepressants** or **antipsychotics.** The risk of having a fit may increase if you take Tramadol oral drops at the same time. Your doctor will tell you whether Tramadol oral drops are suitable for you
- if you are taking certain antidepressants, Tramadol oral drops 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
- if you take coumarin **anticoagulants** (medicines for blood thinning), e.g. warfarin, together with Tramadol oral drops. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol oral drops with food, drink and alcohol

Do not drink alcohol during treatment with Tramadol oral drops as its effect may be intensified. Food does not influence the effect of Tramadol oral drops.

Pregnancy and breast-feeding

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

Pregnancy

There is very little information regarding the safety of tramadol in human pregnancy. Therefore, you should not use Tramadol oral drops if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

Breast-feeding

Tramadol is excreted into breast milk. For this reason, you should not take tramadol more than once during breast-feeding, or alternatively, if you take Tramadol oral drops more than once, you should stop breast-feeding.

Driving and using machines

Tramadol oral drops may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery**.**

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

• do not drive while taking this medicine until you know how it affects you

• it is an offence to drive if this medicine affects your ability to drive

• however, you would not be committing an offence if:

- the medicine has been prescribed to treat a medical or dental problem and
- you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Tramadol oral drops contain sodium and sucrose.

This medicine contains less than 1 mmol sodium(23 mg) per 100mg/ml, that is to say essentially ‘sodium-free’.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE TRAMADOL ORAL DROPS

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.
Unless otherwise prescribed by your doctor, the recommended dose is:

Adults and adolescents from the age of 12 years
The recommended 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. For acute pain, a starting dose of 100 mg is generally required since the effect begins later than with other pain relievers. If Tramadol oral drops are taken for acute pain, the user must be aware that the effect begins somewhat later than with a number of other pain-relievers.
For chronic pain, a starting dose of 50 mg is recommended.

Use in Children
Tramadol oral drops are not suitable for children below the age of 12 years.

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.

Severe liver or kidney disease (insufficiency)/dialysis patients
Patients with severe liver and/or kidney insufficiency should not take Tramadol oral drops. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Tramadol oral drops?
Tramadol oral drops are for oral use.
Mix the drops in one glass of water. Then drink the whole content of the glass.
The drops may be taken before, during or after meals.

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 oral drops than you should

If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed. After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heart beat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing may occur.

In such cases a doctor should be called immediately.

If you forget to take Tramadol oral drops

If you have forgotten to take a dose, pain is likely to return.

Do not take a double dose to make up for forgotten individual doses, simply continue taking drops as before.

If you stop taking Tramadol oral drops

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, 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), and change in perception of reality (derealization) and delusion of persecution (paranoia) have been seen very rarely. If you experience any of these complaints after stopping Tramadol oral drops, please consult your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- 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.

Stop taking this medicine if you experience any of the following:

- Symptoms of severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome), cross reactivity with other painkillers (such as acetylsalicylic acid, ibuprofen, naproxen).
- Thoughts of suicide

Other side effects include:

Very common (may affect more than 1 in 10 people):

- dizziness
- nausea

Common (may affect up to 1 in 10 people):

- headaches
- drowsiness
- constipation
- dry mouth
- vomiting
- indigestion (dyspepsia)
- abdominal pain
- sweating
- menopausal symptoms
- fatigue
- low energy (weakness).

Uncommon (may affect up to 1 in 100 people):

- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse)
- anorexia
- stomach trouble (e.g. feeling of pressure in the stomach, bloating)
- diarrhoea
- skin reactions (e.g. itching, rash).

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

- slow heartbeat
- increase in blood pressure
- changes in appetite
- abnormal sensations (e.g. itching, tingling, numbness)
- trembling, slow breathing
- epileptic fits
- muscle twitches
- uncoordinated movement
- transient loss of consciousness (syncope)
- increased muscle stiffness
- taste disturbance
- hallucinations
- confusion
- sleep disorders
- anxiety and nightmares
- psychological complaints
- change in mood (mostly high spirits, occasionally irritated mood)
- changes in activity (usually suppression, occasionally increase)
- decreased cognitive function
- sensory perception (changes in senses and recognition)
- dependence
- drug abuse and addiction
- miosis (excessive constriction of the pupil of the eye)
- blurred vision
- shortness of breath (dyspnoea)
- worsening of asthma
- weak muscles
- passing urine with difficulty or pain
- passing less urine than normal
- weight loss
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin)
- shock (sudden circulation failure)
- stomach and bowel disorders
- menstrual disorders.

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

- increase in liver enzyme values.

Not known (frequency cannot be estimated based on available data):

- low sodium concentration in the blood
- decrease in blood sugar level
- speech disorders
- excessive dilation of the pupils (mydriasis).

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRAMADOL ORAL DROPS

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 carton and the label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tramadol oral drops contain

-The active substance is tramadol (as the hydrochloride).

Each 1ml oral drops, solution contains 100mg/ml Tramadol (as the hydrochloride).

-The other ingredients are Sucrose, Saccharin sodium, Potassium sorbate (E202), Polysorbate 20, Aniseed oil, Peppermint oil, Purified water and Hydrochloric acid (for pH adjustment).

What Tramadol oral drops look like and contents of the pack

Tramadol oral drops are clear, colourless or faint yellowish solution. They are delivered in boxes containing one, three or five amber glass bottles of 10ml, with an inserted dropper applicator and sealed with a child safe screw cap. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Mercury Pharmaceuticals Ltd, Capital House, 85 King William Street, London EC4N 7BL, UK

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