Package leaflet: Information for the patient

Tramadol hydrochloride Krka 100 mg
prolonged-release tablets
Tramadol hydrochloride Krka 150 mg
prolonged-release tablets
Tramadol hydrochloride Krka 200 mg
prolonged-release tablets

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 hydrochloride Krka is and what it is used for

Tramadol - the active substance in Tramadol hydrochloride Krka - 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 hydrochloride Krka is used for the treatment of moderate to severe pain.

2. What you need to know before you take Tramadol hydrochloride Krka

Do not take Tramadol hydrochloride Krka
- 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 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 before treatment with Tramadol hydrochloride Krka (see "Other medicines and Tramadol hydrochloride Krka");
- if you suffer from epilepsy and your fits are not adequately controlled by treatment;
- as a substitute in drug withdrawal.

Warnings and precautions
Talk to your doctor or pharmacist before taking Tramadol hydrochloride Krka:
- 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 in 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;
- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Other medicines and Tramadol hydrochloride Krka ").

Serotonin syndrome
There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 "Possible side effects").

Sleep-related breathing disorders
Tramadol hydrochloride Krka 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.

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

Please note that Tramadol hydrochloride Krka may lead to physical and psychological addiction.
When Tramadol hydrochloride Krka 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 hydrochloride Krka 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 Tramadol hydrochloride Krka treatment or if they applied to you in the past.

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.

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.

Children and adolescents
The medicine should not be given to children under 12 years of age.
Tramadol is not recommended in children and adolescents with breathing problems, since the symptoms of tramadol toxicity may be worse in these children and adolescents.

Other medicines and Tramadol hydrochloride Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

The pain-relieving effect of Tramadol hydrochloride Krka may be reduced and the length of time it acts may be shortened, if you take medicines which contain
- carbamazepine (for epileptic fits);
- ondansetron (prevents nausea).

Concomitant use of Tramadol hydrochloride Krka 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 hydrochloride Krka 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. Your doctor will tell you whether you should take Tramadol hydrochloride Krka, and which dose.

The risk of side effects increases,
- if you are taking tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol hydrochloride Krka. 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 having a fit may increase if you take Tramadol hydrochloride Krka at the same time. Your doctor will tell you whether Tramadol hydrochloride Krka is suitable for you.
- if you are taking certain antidepressants Tramadol hydrochloride Krka may interact with these medicines and you may experience serotonin syndrome (see section 4 "Possible side effects").
- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol hydrochloride Krka. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol hydrochloride Krka with food and alcohol
Do not drink alcohol during treatment with Tramadol hydrochloride Krka as its effect may be intensified. Food does not influence the effect of Tramadol hydrochloride Krka.

Pregnancy and breast-feeding and fertility

Pregnancy
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. There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Tramadol hydrochloride Krka 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 hydrochloride Krka more than once during breast-feeding, or alternatively, if you take Tramadol hydrochloride Krka more than once, you should stop breast-feeding.

Fertility
Based on human experience tramadol is suggested not to influence female or male fertility.

Driving and using machines
Tramadol hydrochloride Krka 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 hydrochloride Krka contains lactose
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 hydrochloride Krka

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

Your doctor will adjust the dosage according to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken. Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

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KRKA
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Prepared by: D. Primc
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The recommended dose is:
Adults and adolescents from the age of 12 years
- One Tramadol hydrochloride Krka 100 mg tablet twice daily (equivalent to 200 mg tramadol hydrochloride per day) preferably in the morning and evening

If necessary, the dose may be increased up to 150 mg or 200 mg twice daily (equivalent to 300 mg – 400 mg tramadol hydrochloride per day).

Children
Tramadol hydrochloride Krka is 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 hydrochloride Krka.
If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Method of administration
Tramadol hydrochloride Krka prolonged-release tablets are for oral use.

Always swallow Tramadol hydrochloride Krka prolonged-release tablets whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the tablets on an empty stomach or with meals.

How long should you take Tramadol hydrochloride Krka?
You should not take Tramadol hydrochloride Krka 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 hydrochloride Krka and at what dose.

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

If you take more Tramadol hydrochloride Krka 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.

If you (or someone else) swallow a lot of Tramadol hydrochloride Krka tablets at the same time you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, being sick, fall in blood pressure, fast heartbeat, collapse, unconsciousness, fits, and breathing difficulties or shallow breathing.

If you forget to take Tramadol hydrochloride Krka
If you forget to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking the tablets as before.

If you stop taking Tramadol hydrochloride Krka
If you interrupt or finish treatment with Tramadol hydrochloride Krka too soon, pain is likely to return. 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).

If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

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.

Very common: may affect more than 1 in 10 people
- dizziness
- feeling sick (nausea)

Common: may affect up to 1 in 10 people
- headaches, drowsiness
- fatigue
- constipation, dry mouth, being sick (vomiting)
- sweating (hyperhidrosis)

Generally there will be no after-effects when treatment with Tramadol hydrochloride Krka is stopped.
However, on rare occasions, people who have been taking Tramadol hydrochloride Krka 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 “ringing” in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of the own personality (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you experience any of these complaints after stopping Tramadol hydrochloride Krka, please consult your doctor.

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

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). These adverse effects may particularly occur in patients in an upright position or under physical strain
- urge to be sick (retching), 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 1,000 people
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases
- slow heartbeat
- increase in blood pressure
- abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits
- changes in appetite
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- psychological complaints may appear after treatment with Tramadol hydrochloride Krka. Their intensity and nature may vary (according to the patient’s personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (slowing down but sometimes an increase in activity) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement)
- drug dependence may occur. When treatment is stopped abruptly, signs of withdrawal may appear (see “If you stop taking Tramadol hydrochloride Krka”)
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis)
- slow breathing, shortness of breath (dyspnoea)
- worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.
- If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (dysuria)

Very rare: may affect up to 1 in 10,000 people
- hepatic enzymes increased

Not known: frequency cannot be estimated from the available data
- decrease in blood sugar level
- hiccups

Serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 “What you need to know before you take Tramadol hydrochloride Krka”).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: 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 hydrochloride Krka

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

This medicine 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 hydrochloride Krka contains
- The active substance is tramadol hydrochloride.
  Each prolonged-release tablet contains 100 mg tramadol hydrochloride.
  Each prolonged-release tablet contains 150 mg tramadol hydrochloride.
  Each prolonged-release tablet contains 200 mg tramadol hydrochloride.
- The other ingredients are: hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate in the tablet core and hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol, triacetin, red iron oxide (E172) (only for 150 mg and 200 mg prolonged-release tablets), yellow iron oxide (E172) (only for 150 mg and 200 mg prolonged-release tablets) in the film coating. See section 2 “Tramadol hydrochloride Krka contains lactose”.

What Tramadol hydrochloride Krka looks like and contents of the pack
Tramadol hydrochloride Krka 100 mg prolonged-release tablets:
White, round, biconvex, film coated tablets with embossed mark T1 on one side of the tablet.
Tablet diameter: approximately 10 mm.

Tramadol hydrochloride Krka 150 mg prolonged-release tablets:
Pale orange pink, round, biconvex, film coated tablets with embossed mark T2 on one side of the tablet. Tablet diameter: approximately 10 mm.

Tramadol hydrochloride Krka 200 mg prolonged-release tablets:
Off pink, round, biconvex, film coated tablets with embossed mark T3 on one side of the tablet.
Tablet diameter: approximately 10 mm.

Tramadol hydrochloride Krka is available in boxes containing:
- 10, 20, 28, 30, 50, 60, 90, 100 prolonged-release tablets in child-resistant blisters.
- 10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 60 x 1, 90 x 1, 100 x 1 prolonged-release tablet in perforated unit dose child-resistant blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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