Package leaflet: Information for the patient

Tapentadol Krka 50 mg
prolonged-release tablets
Tapentadol Krka 100 mg
prolonged-release tablets
Tapentadol Krka 150 mg
prolonged-release tablets
Tapentadol Krka 200 mg
prolonged-release tablets
Tapentadol Krka 250 mg
prolonged-release tablets

tapentadol

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 Tapentadol Krka is and what it is used for

The full name of your medicine is 'Tapentadol Krka 50 mg, 100 mg, 150 mg, 200 mg or 250 mg prolonged-release tablets'. It is referred to as 'Tapentadol Krka ' in the rest of this leaflet. Prolonged-release means that the active substance releases slowly but equaly into the blood. Therefore the medicine works for a longer time and you can take the medicine only twice a day.

Tapentadol - the active substance in Tapentadol Krka - is a strong painkiller which belongs to the class of opioids. Tapentadol Krka is used in adults for the treatment of severe long-term pain that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take Tapentadol Krka

Do not take Tapentadol Krka
- if you are allergic to tapentadol or any of the other ingredients of this medicine (listed in section 6)
- if you have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia (abnormally elevated carbon dioxide levels in the blood))
- if you have no bowel movement as shown by severe constipation and bloating which may be accompanied by pain or discomfort in the lower stomach
- if you have poisoning with alcohol, sleeping pills, pain relievers or medicines that affect mood and emotions (see 'Other medicines and Tapentadol Krka')

Warnings and precautions
Talk to your doctor or pharmacist before taking Tapentadol Krka if you:
- have slow or shallow breathing
- suffer from increased pressure in the brain or are not fully conscious
- have had a head injury or brain tumors
- suffer from liver or kidney problems (see 'How to take Tapentadol Krka')
- suffer from pancreatic disease including inflammation of the pancreas (pancreatitis) or disease of the bile duct (biliary tract disease)
- are taking medicines referred to as mixed opioid agonist/antagonist (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine)
- have a tendency towards epilepsy or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase
- have a tendency to abuse medicines or if you are dependent on medicines, as Tapentadol Krka may lead to addiction. In this case you should only take these tablets for short periods of time and under strict medical supervision.
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- are a smoker.
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Tapentadol Krka, it is important that you consult your doctor. Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop taking this medicine treatment.

Sleep-related breathing disorders
Tapentadol 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.

Children and adolescents
Tapentadol Krka is not recommended for children and adolescents below the age of 18 years.

Other medicines and Tapentadol Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will tell you which medicines are safe to take with Tapentadol Krka.
- The risk of side effects increases 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 Tapentadol Krka at the same time. Your doctor will tell you whether Tapentadol Krka is suitable for you.
- Concomitant use of Tapentadol Krka and sedative medicines such as benzodiazepines or related drugs (certain sleeping pills or tranquillizers (e.g. barbiturates) or pain relievers such as opioids, morphine and codeine (also as cough medicine), antipsychotics, H1-antihistamines, alcohol) 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 Tapentadol Krka together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
- The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.
- Please tell your doctor if you are taking gabapentin or pregabalin or any sedative medicines 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.
- If you are taking a type of medicine that affects serotonin levels (e.g. certain medicines to treat depression), speak to your doctor before taking Tapentadol Krka as there have been cases of "serotonin syndrome". Serotonin syndrome is a rare, but life-threatening condition. The signs include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38oC. Your doctor can advise you on this.
- Tapentadol Krka may not work as well if taken with opioid like medicines (e.g. those containing pentazocine, nalbuphine or buprenorphine). Tell your doctor if you are currently being treated with one of these medicines.
- Taking Tapentadol Krka with products (e.g. rifampicin, phenobarbital or St John's Wort) that affect the enzymes required to remove Tapentadol Krka from the body, may affect how well Tapentadol Krka works or may cause side effects. The effects may occur especially when the other medication is started or stopped.
- Tapentadol Krka should not be taken together with monoamine oxidase inhibitors (MAOIs - certain medicines for the treatment of depression). Tell your doctor if you are taking MAO inhibitors or have taken these during the last 14 days.

Please keep your doctor informed about all medicines you are taking.

Tapentadol Krka with alcohol
Do not drink alcohol whilst you are taking Tapentadol Krka, because some side effects such as drowsiness may be increased.

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.

Do not take Tapentadol Krka:
- if you are pregnant, unless your doctor has instructed you to do so, if used over prolonged periods during pregnancy, tapentadol may lead to withdrawal symptoms in the newborn baby, which might be life-threatening for the newborn if not recognized and treated by a doctor.
- if you are breast-feeding, as it may pass into the breast milk.
- if you become pregnant during treatment with Tapentadol Krka. Check with your doctor.
- during childbirth, as it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn.

Driving and using machines
If you feel drowsy, dizzy, have blurred vision or a slow reaction time whilst taking Tapentadol Krka, then do not drive, use tools or machinery.

Any such effects are more likely to occur when you start taking Tapentadol Krka, when the dose of Tapentadol Krka is changed, or when you drink alcohol or take tranquilizers.

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.

Tapentadol 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 Tapentadol Krka

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

Your doctor will change the dose and time between doses of Tapentadol Krka according to your pain level and your needs. Generally, the lowest pain-relieving dose should be taken.

Adults
The usual starting dose is 50 mg taken twice daily, approximately every 12 hours.
Your doctor may prescribe a different, more appropriate dose or timing of dosing, if this is necessary for you. If you feel that the effect of these tablets is too strong or weak, talk to your doctor or pharmacist.

Tapentadol Krka should be taken twice daily, approximately every 12 hours.

Total daily doses of Tapentadol Krka greater than 500 mg tapentadol are not recommended.

How and when should you take Tapentadol Krka
Tapentadol Krka is for oral use.

Swallow the tablets whole with a glass of water. You may take the tablets either on an empty stomach or with food. **Do not chew, break or crush the tablet**, as it may result in overdose due to quick release of tapentadol in your body.

The empty shell of the tablet may not be digested completely and thus be seen in stool. This should not worry you, since the drug (active substance) of the tablet has already been absorbed in your body and what you see is just the empty shell.

How long should you take Tapentadol Krka
Do not take the tablets for longer than your doctor has told you.

Elderly
In elderly patients (above 65 years) usually no dose adjustment is necessary. However, your doctor may adjust your dose or time between doses if required.

Hepatic or renal impairment
Do not take Tapentadol Krka if you have severe liver or kidney problems.
If you have moderate liver problems, your doctor will adjust your dose or time between doses.
If you have mild liver problems or mild to moderate kidney problems, a dose adjustment is not required.

Use in children and adolescents
Tapentadol Krka is not recommended for children and adolescents below the age of 18 years.

If you take more Tapentadol Krka than you should
Taking too much Tapentadol Krka may be life-threatening.

Immediate medical advice should be sought in the event of an overdose, even if you feel well.
Very high doses of Tapentadol Krka may cause the following:
- pin-point pupils in the eyes
- being sick (vomiting)
- drop in blood pressure
- fast heart beat
- altered consciousness, collapse or deep unconsciousness (coma)
- epileptic fits
- dangerously slow or shallow breathing or stopping breathing.

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

If you stop taking Tapentadol Krka
If you interrupt or stop treatment too soon, your pain is likely to return. If you wish to stop treatment, please tell your doctor first before stopping treatment.

Generally there will be no withdrawal effects when treatment is stopped. However, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they suddenly stop taking them.

Symptoms may be:
- feeling restless, irritable, anxious, weak or sick (nausea), loss of appetite, being sick (vomiting), diarrhoea
- watery eyes, runny nose, increase in size of the pupils in the eyes (dilated pupils)
- difficulty in sleeping, yawning
- sweating, shivering
- muscle or joint pain, backache, abdominal cramps
- increase in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping Tapentadol Krka, please contact your doctor.
Do not stop taking this medicine unless your doctor tells you to. If your doctor wants you to stop taking your tablets, he/she will tell you how to do this. This may include a gradual reduction of the dose.

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.

Important side effects or symptoms to look out for and what to do if you are affected:
- This medicine may cause allergic reactions including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock (uncommon). Symptoms may be wheeziness, difficulty breathing, swelling of the eyelids, face or lips, or rash or itching, which may cover your whole body.
- Another serious side effect is a condition where you breathe more slowly or weakly than expected (rare). It mostly occurs in elderly and weak patients.

If you are affected by these important side effects contact a doctor immediately.

Other side effects that may occur:

Very common (may affect more than 1 in 10 people)
- feeling sick (nausea)
- constipation
- dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people)
- decreased appetite, anxiety, being sick (vomiting), diarrhoea, indigestion
- sleep problem, tiredness or exhaustion (fatigue), feeling of weakness, trembling, muscle twitches, shortness of breath
- feeling depressed, nervousness, restlessness, lack of attention
- feeling hot (flushing), increased sweating, feeling of body temperature change, dry areas like nostrils, mouth, lips, eyelids, ears, genitals and anus
- itching, rash
- water retention (oedema).

Uncommon (may affect up to 1 in 100 people)
- weight loss
- low awareness of time, place or identity (disorientation), confusion, excitable (agitated), disturbances in perception, abnormal dreams, forgetfulness, mental impairment
- very happy (euphoria), less consciousness, fainting, sedation, feeling unsteady, difficulty in speaking, numbness
- abnormal sensations of the skin (e.g. tingling, prickling), skin reactions (hives)
- abnormal vision
- faster or slower heart beat, palpitations, low blood pressure
- stomach discomfort, delay in passing urine, passing urine more often than usual
- sexual dysfunction
- drug withdrawal effects (see 'If you stop taking Tapentadol Krka ')
- feeling strange, irritable.

Rare (may affect up to 1 in 1,000 people)
- addiction
- thinking abnormal, epileptic fits, near fainting, uncoordinated, feeling drunk or relaxed
- delayed emptying of the stomach (impaired gastric emptying).

Unknown
- delirium

In general, the likelihood of having suicidal thoughts and behaviour is increased in patients suffering from chronic pain. In addition, certain medicines for the treatment of depression (which have an impact on the neurotransmitter system in the brain) may increase this risk, especially at the beginning of treatment. Although tapentadol also affects neurotransmitters, data from human use of tapentadol do not provide evidence for an increased risk.

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 Tapentadol 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 Tapentadol Krka contains
- The active substance is tapentadol.
  Tapentadol Krka 50 mg prolonged-release tablets
  Each prolonged-release tablet contains tapentadol maleate hemihydrate equivalent to 50 mg tapentadol.
  Tapentadol Krka 100 mg prolonged-release tablets
  Each prolonged-release tablet contains tapentadol maleate hemihydrate equivalent to 100 mg tapentadol.
  Tapentadol Krka 150 mg prolonged-release tablets
  Each prolonged-release tablet contains tapentadol maleate hemihydrate equivalent to 150 mg tapentadol.
  Tapentadol Krka 200 mg prolonged-release tablets
  Each prolonged-release tablet contains tapentadol maleate hemihydrate equivalent to 200 mg tapentadol.
  Tapentadol Krka 250 mg prolonged-release tablets
  Each prolonged-release tablet contains tapentadol maleate hemihydrate equivalent to 250 mg tapentadol.
- The other ingredients (excipients) are:
  - Tablet Core:
    hypromellose, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate;
  - Film-Coating Layer:
    hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol, triacetin, yellow iron oxide (E172) *(only for 100 mg, 150 mg, 200 mg and 250 mg)*, red iron oxide (E172) *(only for 150 mg, 200 mg and 250 mg)* and black iron oxide (E172) *(only for 250 mg)*. See section 2: "Tapentadol Krka contains lactose."

What Tapentadol Krka looks like and contents of the pack
Tapentadol Krka 50 mg prolonged-release tablets:
White or almost white, oval, biconvex, film-coated tablets with mark T1 on one side of the tablet. Tablet dimensions: approx. 16 mm x 8.5 mm.
Tapentadol Krka 100 mg prolonged-release tablets:
Pale brownish yellow, oval, biconvex, film-coated tablets with mark T2 on one side of the tablet. Tablet dimensions: approx. 16 mm x 8.5 mm.
Tapentadol Krka 150 mg prolonged-release tablets:
Pale pink, oval, biconvex, film-coated tablets with mark T3 on one side of the tablet. Tablet dimensions: approx. 16 mm x 8.5 mm.
Tapentadol Krka 200 mg prolonged-release tablets:
Pale brownish orange, oval, biconvex, film-coated tablets with mark T4 on one side of the tablet. Tablet dimensions: approx. 18 mm x 8 mm.
Tapentadol Krka 250 mg prolonged-release tablets:
Off pink, oval, biconvex, film-coated tablets with mark T5 on one side of the tablet. Tablet dimensions: approx. 18 mm x 8 mm.

Tapentadol Krka is available in boxes containing 20 (*only for 50 mg*), 28, 30, 56 (2 x 28), 60 (2 x 30) or 100 prolonged-release tablets in polyethylene (HDPE) tablet container with a child resistant tamper-evident polypropylene (PP) closure.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Manufacturer:
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