

TRAMADOL CAPSULES

Tramadol hydrochloride (50 mg)

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What *Tramadol* is used for

Tramadol is used for the treatment of moderate to severe pain.

How *Tramadol* works

Tramadol – the active substance in *Tramadol capsules* - 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.

Before you use *Tramadol*

- When you must not use it

- if you are allergic (hypersensitive) to tramadol or any of the other ingredients of *Tramadol*
- in acute poisoning with alcohol, sleeping pills, pain relievers (e.g. analgesics, opioids) 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 before treatment with *Tramadol* (see "Taking other medicines")
- if you are an epileptic and your fits are not adequately controlled by treatment
- as a substitute in drug withdrawal

- Before you start use it

Take special care with *Tramadol*:

- 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

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 increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

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

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. *Tramadol* should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of *Tramadol* 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*, and what 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*. 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* 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 serotonin syndrome 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*. The effect of these medicines on blood clotting may be affected and bleeding may occur.

How to use *Tramadol*

- How much to use

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 usual dose is:

Adults and adolescents from the age of 12 years

Acute Pain: An initial dose of 100 mg is usually necessary. This can be followed by doses of 50 or 100mg not more frequently than 4 hourly, and duration of therapy should be determined by your doctor.

Pain associated with chronic conditions: Use an initial dose of 50 mg and your doctor might adjust your dose according to the severity of pain.

Your doctor may prescribe a different, more appropriate dosage of *Tramadol* if necessary. Do not take more than 8 *Tramadol capsules* (equivalent to 400 mg tramadol hydrochloride) daily,

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except if your doctor has instructed you to do so.

Children

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

- When to use it

Tramadol capsules are for oral use. Always swallow *Tramadol* whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

- How long to use it

You should not take *Tramadol* 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* and at what dose.

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

- If you forget to use it

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

- If you use too much (overdose)

If you (or someone else) swallow a lot of *Tramadol* 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, a fall in blood pressure, a fast heartbeat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing.

While you are using it

- Things you must do

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

- Things you must not do

Tramadol 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, and do not work without a firm hold!

- Things to be careful of

Ask your doctor or pharmacist for advice before taking any medicine. There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use *Tramadol* if you are pregnant.

Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

Generally, the use of tramadol is not recommended during breast-feeding. Small amounts of tramadol are excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

Side effects

Like all medicines, *Tramadol* can cause side effects, although not everybody gets them.

In case one of the following situations occurs, see your doctor straight away:

- allergic reactions e.g. difficulty in breathing, wheezing, swelling of skin (occurs rarely)
- swollen face, tongue and/or throat and/or difficulty to swallow or hives together with difficulties in breathing (occurs rarely)
- shock/sudden circulation failure (occurs rarely)

The most common side effects during treatment with *Tramadol* are nausea and dizziness.

Heart and blood circulation disorders

Uncommon: 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.

Rare: slow heartbeat, increase in blood pressure.

Nervous system disorders

Very common: dizziness.

Common: headaches, drowsiness.

Rare: changes in appetite, abnormal sensations (e.g. itching, tingling, numbness), trembling, slow breathing, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope).

If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.

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.

Psychiatric disorders

Rare: hallucinations, confusion, sleep disorders, anxiety and nightmares.

Psychological complaints may appear after treatment with *Tramadol*. 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 being less aware and less able to make decisions, which may lead to errors in judgment.

Dependence may occur.

Eye disorders

Rare: blurred vision.

Respiratory disorders

Rare: shortness of breath (dyspnoea). Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.

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Stomach and bowel disorders

Very common: feeling sick.

Common: being sick, constipation, dry mouth.

Uncommon: urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea.

Skin disorders

Common: sweating

Uncommon: skin reactions (e.g. itching, rash).

Muscle disorders

Rare: weak muscles.

Liver and biliary disorders

Very rare: increase in liver enzyme values.

Urinary disorders

Rare: passing water difficult or painful, less urine than normal.

General disorders

Common: tiredness, weariness, weakness, low energy.

There have been some reports of speech disorders and dilated pupils.

If *Tramadol* capsules are taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly signs of withdrawal may appear.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of *Tramadol*

- Storage

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

Do not store above 25°C.

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

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

The capsules are white and blue; the capsules contain a white powder.

Supply

20 capsules in a box

- Ingredients

Active ingredient:

The active substance is tramadol hydrochloride.

Each capsule contains 50 mg tramadol hydrochloride.

Inactive ingredients:

The other ingredients of the capsules are microcrystalline cellulose, sodium starch glycolate, talc and magnesium stearate in the capsule core.

- MAL number:

MAL19973621AZ

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Product Registration Holder

PAHANG PHARMACY SDN. BHD.,
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