Package leaflet: Information for the user

Tramadol STADA 50 mg capsules, hard

Active substance: 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 STADA is and what it is used for

Tramadol - the active substance in Tramadol STADA - is a painkiller belonging to the class of the opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Tramadol STADA is used
- Treatment of moderate to severe pain.

2. What you need to know before you take Tramadol STADA

DO NOT take Tramadol STADA
- if you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- in acute poisoning with alcohol, sleeping pills, painkillers or other psychotropic medicines (medicines that affect mood and emotions)
- if you are also taking monoamine oxidase (MAO) inhibitors (medicines used to treat depression)
- if you have taken MAO inhibitors within two weeks of when you will start taking Tramadol STADA
- if you are an epileptic and your fits are not adequately controlled by treatment
- as a substitute drug in drug withdrawal treatment

Warnings and precautions
Talk to your doctor or pharmacist before taking Tramadol STADA
- if you have a tendency towards epilepsy or fits because the risk of a fit may increase. Normal doses of Tramadol STADA can cause seizures (fits). Higher doses of Tramadol STADA can increase the risk of seizures. The risk of seizures is also higher when Tramadol STADA is taken with other medicines (see “Other medicines and Tramadol STADA”).
- if you have a head injury

- if the pressure inside your skull is higher than normal. This can happen after a head injury or can be due to a brain disease such as a brain tumour.
- if you are in shock (signs of shock include cold sweats)
- if you have difficulty in breathing
- if you suffer from consciousness disorders (if you feel that you are going to faint)
- if you suffer from a liver or kidney disease
- if you think that you are addicted to other painkillers (opioids)

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
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.

Drug dependence
Please note that Tramadol STADA may lead to physical and psychological addiction. When Tramadol STADA is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development).

If your doctor thinks you are at risk of developing dependence, he will treat you with Tramadol STADA for short periods. Your doctor will also regularly check if you need to continue taking Tramadol STADA.

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

DO NOT take Tramadol STADA with monoamine oxidase inhibitors (MAO), or 2 weeks before and after taking these medicines. MAOs are medicines used for depression.

The effect of Tramadol STADA may be greater if:
- you are also taking other medicines which act on your central nervous system e.g. tranquillisers, sleeping pills, other painkillers such as morphine and codeine (also as cough medicine).
- you are drinking alcohol (see also “Driving and using machines”)

You may feel drowsier or feel that you might faint. If this happens tell your doctor.

The pain-relieving effect of Tramadol STADA can be reduced and the duration of effect be shortened if:
- you take medicines containing ondansetron (against nausea)
- you also take carbamazepine (a medicine for epilepsy and mental disorders)

You should not take Tramadol STADA together with the following painkillers:
- buprenorphine
- nalbuphine
- pentazocine

The risk of side effects increases,
- 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 STADA at the same time. Your doctor will tell you whether Tramadol STADA is suitable for you.
- if you are taking certain antidepressants. Tramadol STADA 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. These might be signs of a so-called “serotonin syndrome”.

You should take care if you are also taking blood-thinning drugs (e.g. warfarin). Tramadol STADA can increase the clotting time of your blood and cause spots of bleeding in the skin (ecchymoses).

If you take ondansetron - a medicine to stop you from vomiting (being sick), you may need to take more Tramadol STADA. Your doctor will decide your dose. Ondansetron is often used during cancer treatment (chemotherapy) or before or after an operation.

Concomitant use of Tramadol STADA 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 STADA 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.

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

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 little information on the safety of Tramadol STADA in human pregnancy.

This medicine may harm your unborn child. If you are planning to become pregnant or are already pregnant:
- you should only use Tramadol STADA if your doctor tells you to. Your doctor will decide if you should take Tramadol STADA

If your doctor decides that you should take Tramadol STADA during pregnancy he will give you only single doses. You should not take Tramadol STADA long-term during pregnancy. This may affect your unborn child who may develop withdrawal symptoms.

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

Driving and using machines
Tramadol STADA 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.

Tramadol STADA contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Tramadol STADA

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.

Do not take doses more often than every 4 hours.

The painkilling effect of Tramadol STADA will last for 4 to 8 hours depending on the intensity of your pain.

Your doctor will treat you with Tramadol STADA for short periods with regular breaks. This will minimise the risk of you developing dependence (see "Warnings and precautions").

Do not take more than a total of 400 mg tramadol hydrochloride (8 capsules, hard of Tramadol STADA) per day unless your doctor has explicitly prescribed it otherwise.

Use in children up to 12 years
Children up to 12 years of age should not take Tramadol STADA capsules. Other forms of Tramadol STADA are available that are more suitable for young children.

Adults and adolescents over 12 years
The usual single dose is 1 - 2 capsules Tramadol STADA (equivalent to 50 – 100 mg tramadol hydrochloride) 3 to 4 times a day.

If pain control is still inadequate 30 - 60 minutes after administration of 1 capsule (50 mg) Tramadol STADA administration of another single dose of 1 capsule Tramadol STADA (50 mg) is possible.

In case of severe pain your doctor will decide if 2 capsules of Tramadol STADA (equivalent to 100 mg Tramadol hydrochloride) should be administered. If pain relief is still not achieved, your doctor will increase your dose of Tramadol STADA until satisfactory pain relief is archived.

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

Method of administration
You should swallow your Tramadol STADA capsules, hard whole with water. Do not crush or chew them. You should take Tramadol STADA between meals.

Duration of treatment
Your doctor will tell you for how long you should take Tramadol STADA.

If you take more Tramadol STADA 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 contact your doctor or go to your nearest emergency department immediately!

Remember to take the pack and any remaining capsules with you.

Your doctor will treat the symptoms of Tramadol STADA overdose.

If you forget to take Tramadol STADA
If you forget to take the capsules, pain is likely to return. If you forget to take a dose of Tramadol STADA just take the next dose at the usual time. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Tramadol STADA
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 interrupt or finish treatment with Tramadol STADA too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

Generally there will be no after-effects when treatment with Tramadol STADA is stopped. However, on rare occasions, people who have been taking Tramadol STADA 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 STADA, 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.

Stop taking the medicine and contact your doctor immediately if you get:
Symptoms of an allergic reaction, such as:
- swollen face, extremities, tongue, voice box or throat
- difficulty swallowing
- difficulty breathing
- hives and difficulty breathing

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

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

Uncommon (may affect up to 1 in 100 people):
- urge to vomit (retching)
- gastrointestinal irritation (a feeling of pressure in the stomach, bloating)
- diarrhoea
- effects on cardiovascular regulation including feeling your heartbeat (palpitations), rapid heartbeat (tachycardia), feeling dizzy or faint when standing up (postural hypotension), when there is not enough circulation of blood because the heart does not work properly (cardiovascular collapse).
  These side effects are more likely if you are physically stressed. For example if you have just had an operation.
- skin reactions including:
  - itching (pruritus)
  - rash
  - hives (urticaria)

Rare (may affect up to 1 in 1,000 people):
- changes in appetite
- slow heartbeat (bradycardia)
- increase in blood pressure
- slow or shallow breathing (respiratory depression). You may develop respiratory depression if:
  - you take much more than the recommended dose (see Section 3 “If you take more Tramadol STADA than you should”) and
  - you take other substances which depress the central nervous system (see “Other medicines and Tramadol STADA”)
- epileptic fits. These are more likely to occur:
  - after high doses of Tramadol STADA or
  - after taking drugs which cause fits or make fits more likely. For example, antidepressants or anti-psychotic medicines (see “Other medicines and Tramadol STADA”).
- muscle twitches
- pins and needles (paraesthesia)
- shaking (tremor)
- psychological complaints may occur following administration of tramadol. These vary in intensity and type depending on:
  - your personality
  - how long you take Tramadol STADA

  These include:
  - changes in mood – usually high spirits (elation), occasionally an unpleasant mood (dysphoria)
  - changes in activity (usually less active, occasionally more active)
  - changes in your ability to think and feel things clearly (your cognitive and sensorial capacity) such as:
    - making decisions (decision behaviour)
    - lack of awareness or understanding (perception disorders)

  - seeing or hearing things that are not real (hallucinations)
  - confusion
  - sleep disturbances
  - delirium
  - bad dreams (nightmares)
- blurred vision
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal
- uncoordinated movement
- transient loss of consciousness (syncope)
- anxiety
- allergic (hypersensitivity) reactions including:
  - shortness of breath (dyspnoea)
  - constriction of the lower airways causing difficulties in breathing (bronchospasm)
  - wheezing
  - angioedema/severe allergic reactions/shock with difficulties to breath

At the end of medication, when treatment is stopped abruptly signs of withdrawal may appear (see “If you stop taking Tramadol STADA”).

Very rare (may affect up to 1 in 10,000 people):
- drug dependence
- increase in liver enzyme values

Not known (frequency cannot be estimated from the available data):
- worsening of asthma has been reported, however it has not been established whether it was caused by tramadol
- excessive dilation of the pupils (mydriasis)
- speech disorders
- decrease in blood sugar level (hypoglycaemia)

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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tramadol STADA

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 blister and the carton. The expiry date refers to the last day of that month.

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 STADA contains

The active substance is tramadol hydrochloride.

One capsule, hard of Tramadol STADA contains 50 mg tramadol hydrochloride.

The other ingredients are:

Capsules content
- calcium hydrogen phosphate dihydrate
- magnesium stearate
- colloidal anhydrous silica

Capsule shell
- gelatin
- titanium dioxide (E171)
- sodium lauryl sulphate

What Tramadol STADA looks like and contents of the pack
Tramadol STADA capsules, hard, white, opaque, capsules.

Tramadol STADA capsules, hard are packaged in aluminium/PVC blisters.

Packs of Tramadol STADA 50 mg hard capsules containing 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 200, 250, 500 and 1000 capsules, hard.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
To be completed nationally.

Manufacturer
To be completed nationally.

This medicinal product is authorised in the Member States of the EEA under the following names:
BE: Tramadol EG 50 mg
DK: Tadol, kapsler, harde 50 mg
DE: Tramadol STADA 50 mg Hartkapseln
IT: Tramadolo EG
LU: Tramadol-EG CPS 50 mg
NL: Tramadol HCl capsule CF 50 mg
SE: Tramadol Stada, kapsel, hard 50 mg

This leaflet was last revised in January 2020.