PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

Tramadol Injection 50 mg/ml Pharma-Q solution for injection

Tramadol Injection 100 mg/2 ml Pharma-Q solution for injection

Tramadol hydrochloride

Sugar free

Read all of this leaflet carefully before you are given Tramadol Injection Pharma-Q

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Tramadol Injection Pharma-Q has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Tramadol Injection Pharma-Q is and what it is used for

Tramadol Injection Pharma-Q contains tramadol, which belongs to a group of medicines known as analgesics or “pain-killers”.

Tramadol Injection Pharma-Q is used to relieve and manage moderate to moderately severe pain.

2. What you need to know before you are given Tramadol Injection Pharma-Q

Tramadol Injection Pharma-Q should not be administered to you:

- If you are hypersensitive (allergic) to tramadol hydrochloride or any of the other ingredients of Tramadol Injection Pharma-Q (listed in section 6).
- If you are epileptic and your fits are not well controlled by treatment.
- If the patient is a child under 12 years of age.
- If you are taking any of the following medicines:
  - sleeping tablets or tranquillizers such as nitrazepam
  - other pain-killers such as codeine or morphine
  - psychotropic medicines such as chlorpromazine
  - a monoamine oxidase inhibitor used to treat depression, or if you have taken one in the past two weeks
- If you have recently been drinking alcohol.
- It should not be used in narcotic drug withdrawal treatment.
- If you are pregnant or breastfeeding your baby.
- If you have respiratory depression, which causes you to breath slowly and ineffectively, especially if you also have cyanosis (which causes bluish discoloration of the skin and mucous membranes due to a lack of oxygen in the blood) and excessive bronchial secretions.

- If you have had a head injury or cerebral disease (a variety of medical conditions causing damage to the arteries supplying oxygen and nutrients to the brain) which causes increased intracranial pressure or central nervous depression.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have liver or kidney disease. You may need a lower dose or a longer interval between doses.
- If you have a head injury or brain disease or infection.
- If you have a problem that makes you faint or feel faint.
- If you are in a state of shock. You may feel light-headed, faint, cold or clammy or look pale.
- If you suffer from epilepsy, convulsions or seizures (fits) or have had them in the past.
- If you are suffering from a metabolic disorder, such as diabetes.
- If you suffer from asthma, other lung diseases or have difficulty in breathing.
- If you think you may be addicted to other pain relievers (opioids such as morphine) or alcohol.
- If your child is under the age of 12 years, as Tramadol Injection Pharma-Q is not suitable for children under the age of 12 years.

Tramadol may lead to addiction

In patients with a tendency to drug abuse, Tramadol Injection Pharma-Q should only be given for short periods under strict medical supervision.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 receiving Tramadol Injection Pharma-Q and seek medical advice:

slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Use in children with breathing problems

Tramadol Injection Pharma-Q is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Other medicines and Tramadol Injection Pharma-Q

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking, or have recently taken, any of the following medicines. This is important because Tramadol Injection Pharma-Q could alter how other medicines work.

- Serotonin – norepinephrine reuptake inhibitors (SNRI's) tricyclic antidepressants, antipsychotics and other seizure threshold-lowering medicines (such as bupropion, mirtazapine, (tetrahydrocannabinol) to cause convulsions.
- Carbamazepine, a treatment for epilepsy, as this may reduce the effectiveness of the tramadol.
- Triptans, such as sumatriptan, used to treat migraines, as this may increase the effectiveness of the triptans.
- Coumarin anticoagulants, used to thin the blood, such as warfarin, as this may alter the effectiveness of the anticoagulant.
- Selective serotonin reuptake inhibitors (SSRI's), used to treat depression, such as fluoxetine, as this may increase the effect of the SSRI's.
- Lithium, used to treat psychotropic disorders, as this may alter the effect of lithium.
- Ondansetron, used to prevent nausea and vomiting.
- Other active substances known to inhibit CYP3A4, such as ketoconazole and erythromycin, might inhibit the metabolism of tramadol. The concomitant use of opioids

with sedating medicines such as benzodiazepines or related products increases the risk of respiratory depression, sedation, coma and death because of additive CNS depressant effect. The dose of Tramadol Injection Pharma-Q and the duration of the concomitant use should be limited.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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 are given Tramadol Injection Pharma-Q at the same time. Your doctor will tell you whether Tramadol Injection Pharma-Q is suitable for you.
- - if you are taking certain antidepressants. Tramadol Injection Pharma-Q 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.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving Tramadol Injection Pharma-Q.

There is very little information on the safety of tramadol in pregnancy, therefore Tramadol Injection Pharma-Q should not be used if you are pregnant.

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

Tramadol is excreted into breast milk. For this reason, you should not receive Tramadol Injection Pharma-Q.

Driving and using machines

Tramadol Injection Pharma-Q may cause drowsiness, dizziness or blurred vision, these effects may be increased by alcohol and other depressants. Do not drive or use machinery if you are affected.

3. How to receive Tramadol Injection Pharma-Q

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself Tramadol Injection Pharma-Q. You will be given your Tramadol Injection Pharma-Q by a doctor or nurse who is qualified to do so. You may be given Tramadol Injection Pharma-Q by an injection into either a vein or muscle. If you are in hospital you may receive tramadol through a drip (infusion).

The usual dose is one injection of 50 mg or 100 mg every 4 to 6 hours. After an operation you may need injections more often.

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity.

In general, the lowest dose to relieve pain should be given for the shortest possible time.

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 should not be given Tramadol Injection Pharma-Q. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Children: Tramadol Injection Pharma-Q should not be given to children under 12 years of age.

If you have the impression that the effect of Tramadol Injection Pharma-Q is too strong or too weak, tell your doctor or pharmacist.

If you receive more Tramadol Injection Pharma-Q than you should

Since a health care provider will administer Tramadol Injection Pharma-Q, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. If you think you have been given or have given yourself too much Tramadol Injection Pharma-Q, tell a doctor or nurse immediately. Symptoms of intoxication are similar to those of other centrally acting analgesics (opioids) are to be expected. These include in particular miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest.

If you missed a dose of Tramadol Injection Pharma-Q

Since a health care provider will administer Tramadol Injection Pharma-Q, it is unlikely that the dose will be missed.

If you stop receiving Tramadol Injection Pharma-Q

You should not suddenly stop receiving Tramadol Injection Pharma-Q unless your doctor tells you to. If you want to stop receiving Tramadol Injection Pharma-Q, discuss this with your doctor first, particularly if you have been receiving it for a long time.

When some people stop treatment with Tramadol Injection Pharma-Q they get withdrawal symptoms. These symptoms include agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms. Other symptoms that have less frequently been seen with Tramadol Injection Pharma-Q discontinuation include: panic attacks, severe anxiety, hallucinations, paraesthesia, tinnitus and unusual CNS symptoms (i.e. confusion, delusions, personalisation, derealisation, paranoia).

4. Possible side effects

Tramadol Injection Pharma-Q can have side effects.

Not all side effects reported for Tramadol Injection Pharma-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

receiving Tramadol Injection Pharma-Q, please consult your health care provider for advice.

If any of the following happens, stop receiving Tramadol Injection Pharma-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to Tramadol Injection Pharma-Q. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in heart beat or rhythm which may make you feeling faint or dizzy especially if you stand up quickly,
- slowing of the heart rate, increased blood pressure,
- withdrawal symptoms (including agitation, nervousness, shaking, hyperactivity and difficulty in sleeping).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- nausea, dizziness,
- headache, drowsiness, fatigue, vomiting, constipation, dry mouth, sweating,
- dermal reactions – rash, itching, hives,
- changes in appetite, abnormal touch sensations, trembling, difficulty breathing, fits,

fainting, speech disorders,

- nightmares, disturbed sleep patterns, hallucinations (seeing things), feeling confused, changes in mood, activity or awareness, anxiety, delirium,
- blurred vision, excessive dilation or constriction of the pupils,
- muscle weakness or twitching, abnormal coordination,
- increase in liver enzymes,
- difficulty or pain passing water (urine),
- worsening of asthma, shortness of breath,
- panic attacks, severe anxiety, hallucinations, tinnitus or abnormal skin sensations, as well as confusion, delusions, personalisation, derealisation and paranoia.

Frequency unknown

- low blood sugar levels (hypoglycaemia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/.

By reporting side effects, you can help provide more information on the safety of Tramadol Injection Pharma-Q.

5. How to store Tramadol Injection Pharma-Q

Store all medicines out of reach of children.

- Store at or below 25 °C in a cool dry place.
- Do not use after the expiry date stated on the label or carton.

The prepared infusion solution will be made up immediately before use.

Tramadol Injection Pharma-Q is physically and chemically compatible for up to:

- 24 hours with 4,2 % sodium bicarbonate and Ringer's solution.

Or up to 5 days with the following infusion solutions:

- 0,9 % sodium chloride
- 0,18 % sodium chloride and 4 % glucose
- sodium lactate compound
- 5 % glucose

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Tramadol Injection Pharma-Q contains

- The active substance is tramadol hydrochloride.

  Each 1 ml solution contains tramadol hydrochloride 50 mg.

  Each 2 ml solution contains tramadol hydrochloride 100 mg.

  Sugar free.
- The other ingredients are sodium acetate trihydrate and water for injection.

What Tramadol Injection Pharma-Q looks like and contents of the pack

Tramadol Injection Pharma-Q is a clear colourless liquid filled in clear glass ampoules.

Tramadol Injection 50 mg/ml Pharma-Q is packed in a 2 ml clear glass type 1 ampoule with green snap-off.

Tramadol Injection 100 mg/2 ml Pharma-Q is packed in a 2 ml clear glass type 1 ampoule with red snap-off.

Pack sizes: 1, 2, 5, 10 or 20 ampoules per carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pharma-Q Holdings (Pty) Ltd

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Industria West, 2093

Johannesburg

This leaflet was last revised in

09 July 2024

Registration numbers

Tramadol Injection 50 mg/ml Pharma-Q: 47/2.9/1178

Tramadol Injection 100 mg/2 ml Pharma-Q: 47/2.9/1179

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.