

Approved Patient Information Leaflet for Medicines for Human Use:

EPSTELL

SCHEDULING STATUS: S5

EPSTELL 50 mg Capsules

Tramadol hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking EPSTELL

- 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.
- EPSTELL 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 EPSTELL is and what it is used for
2. What you need to know before you take EPSTELL
3. How to take EPSTELL
4. Possible side effects
5. How to store EPSTELL
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1. What EPSTELL is and what it is used for

Tramadol, the active substance in EPSTELL capsules, is a painkiller belonging to the class of the opioids that acts on the central nervous system.

EPSTELL capsules are used for the management of moderate to moderately severe pain.

2. What you need to know before you take EPSTELL

Do not take EPSTELL capsules

- If you are hypersensitive (allergic) to tramadol, opioids or any ingredients in EPSTELL (listed in section 6).
- if you are younger than 12 years of age
- if you are younger than 18 years of age following tonsillectomy (surgical removal of the tonsils) and/or adenoidectomy (surgical removal of the adenoids)
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- if you are taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with EPSTELL capsules
- if you have epilepsy
- as a substitute in drug withdrawal
- if you have difficulty breathing or breathing problems (respiratory depression) especially in the presence of cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes) and excessive bronchial secretions
- if you have previously had head injuries, brain tumour or if you have a condition in which the pressure in your skull has increased
- if you are pregnant or breastfeeding your baby (see Pregnancy and Breastfeeding).

Warnings and precautions

Take special care with EPSTELL if you

- are or have ever been addicted to opioids, alcohol, prescription medicines or illegal medicines
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating when you have stopped taking alcohol or drugs
- feel you need to take more of EPSTELL to get the same level of pain relief, this may mean you are becoming tolerant to the effects of EPSTELL or are becoming addicted to it. Speak to your doctor

who will discuss your treatment and may change your dose or switch you to an alternative pain reliever

- suffer from consciousness disorders (if you feel that you are going to faint)
- are in a state of shock (cold sweat may be a sign of this)
- suffer from increased pressure in the brain (possibly after a head injury or brain disease)
- have difficulty in breathing
- have a history of epilepsy or are susceptible to seizures (“fits”) because the risk of a fit may increase
- suffer from a liver or kidney disease
- suffer from depression and you are taking antidepressants as some of them may interact with EPSTELL (see “Other medicines and EPSTELL”)

Sleep-related breathing disorders

EPSTELL contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood).

The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea.

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

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).

Taking EPSTELL regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of EPSTELL can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking EPSTELL. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids as in EPSTELL should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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 EPSTELL and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

You may experience low levels of sodium in the blood (hyponatraemia) while taking this medicine. Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking EPSTELL, consult with your doctor immediately

Talk to your doctor if you experience any of the following symptoms while taking EPSTELL:

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.

Children and adolescents

EPSTELL is not suitable for children under the age of 12 years.

EPSTELL is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Other medicines and EPSTELL

Always tell your health care provider if you are taking any other medicine.

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

The pain-relieving effect of EPSTELL 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).

Your doctor will tell you whether you should take EPSTELL, and which dose.

The risk of side effects increases,

- if you are taking other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking EPSTELL. You may feel drowsier or feel that you might faint. If this happens tell your doctor.

- Concomitant use of EPSTELL and tranquillizers or sleeping pills (e.g. benzodiazepines), 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 prescribes EPSTELL together with sedating medicines the dose and the duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating 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
- 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 EPSTELL at the same time. Your doctor will tell you whether EPSTELL is suitable for you.
- if you are taking certain antidepressants EPSTELL 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 EPSTELL. The effect of these medicines on blood clotting may be affected and bleeding may occur.

EPSTELL with food and drink

Take EPSTELL capsules with a drink of water.

Take with or without food.

You are advised not to drink alcohol while taking EPSTELL.

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 taking EPSTELL.

If EPSTELL capsules are used on a long-term basis during pregnancy, it will lead to harm (withdrawal symptoms) in newborns.

You should not take EPSTELL capsules if you are pregnant.

The use of EPSTELL capsules is not recommended during breastfeeding. EPSTELL is excreted into breast milk. If you are taking EPSTELL capsules you should not breastfeed your baby.

Driving and using machines

EPSTELL 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.

3. How to take EPSTELL

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

Always take EPSTELL 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. The lowest pain-relieving dose should be taken.

Do not take more than 8 capsules (400 mg) in a 24-hour period.

Adults and children over 12 years:

Moderate pain: Take an initial dose of 50 mg tramadol (1 EPSTELL capsule), followed by 50 mg or 100 mg every 4 to 6 hours.

Severe pain: Take an initial dose of 100 mg followed by 50 mg or 100 mg every 4 to 6 hours.

Elderly patients (above 75 years)

A dose reduction and/or prolongation of the interval between doses are recommended.

Liver or kidney disease (insufficiency)/dialysis patients

If you suffer from liver and/or kidney insufficiency, the excretion of EPSTELL capsules may be delayed. Your doctor may direct you to prolong your dosage intervals.

Duration of administration

You should not take EPSTELL capsules for longer than absolutely 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 EPSTELL capsules and at what dose.

Method of administration

Capsules are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

If you take more EPSTELL than you should

If you have taken too much EPSTELL you may experience pinprick pupils, heart problems, difficulty breathing, seizures “fits” and cold, clammy skin.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take EPSTELL

If you forgot to take a dose, take it as soon as you remember and then take the next dose at the right time. Do not take a double dose to make up for a missed dose.

If you stop taking EPSTELL

If you stop taking EPSTELL, your pain may come back. Some people may become dependent on medicines containing tramadol. If you want to stop taking EPSTELL, contact your doctor who will gradually decrease the dose you are taking.

4. Possible side effects

EPSTELL can have side effects.

Not all side effects reported for EPSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EPSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking EPSTELL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- wheezing, difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and /or throat, which may cause difficulty in swallowing, collapse. These may be signs of a serious allergic reaction.
- rash, swelling or itching of skin
- slowed breathing usually when high doses of EPSTELL are taken.
- shock (sudden circulation failure).

These are very serious side effects. If you have them, you may have had a serious reaction to EPSTELL. 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:

Less frequent:

- Seizures ("fits"),
- Feeling faint or collapsing.
- loss of consciousness
- slow breathing
- shortness of breath

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea (feeling “sick”), vomiting, dry mouth, indigestion, constipation, diarrhoea, lack of appetite, pain in the stomach,
- Sweating, dizziness, headaches.

Less frequent side effects:

- hallucinations (seeing or hearing things that are not there), feeling confused or forgetting (“memory loss”), sleepiness or drowsiness,
- postural hypotension (feeling dizzy or light-headed when standing up after you have been sitting or lying down), flushing
- sleep disorders
- delirium
- anxiety
- nightmares
- changes in mood for example you may feel happy or irritated
- decreased activity
- restlessness
- changes in the way you see or view things
- speech disorder
- muscle twitches
- tingling of skin “pins and needles”
- blurred vision, dilation of the pupil, constriction of the pupil
- changes in heartbeat, dysrhythmias (abnormal rhythm of heart), palpitation (heartbeat very fast in an irregular way), increase in blood pressure.
- increase in liver enzymes (seen on a blood test)
- needing to urinate frequently or difficulty urinating
- itching of the skin, hives, fluid filled rash, skin rash
- muscle weakness

Side effects with frequency unknown:

- drug dependence
- 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).
- Low blood sugar level (hypoglycaemia)
- Hiccups

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of EPSTELL.

5. How to store EPSTELL

Store all medicines out of reach of children

Store in a cool dry place at or below 25 °C. Protect from light.

Keep in outer carton until required for use.

Do not transfer the medicine to any other container.

Do not use after the date, which is stamped on the pack.

Return all unused medicines to your doctor or pharmacist.

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

6. Contents of the pack and other information

What EPSTELL contains

- The active substance is tramadol hydrochloride.
- The other ingredients are colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose and sodium starch glycolate. The capsule shell is composed of ferric oxide yellow, gelatin, indigo carmine, methyl paraben, propyl paraben, sodium lauryl sulphate and titanium dioxide.

What EPSTELL looks like and contents of the pack

EPSTELL 50 mg capsules

Green/Yellow coloured hard gelatin capsules, size 3 filled with a homogeneous white to off white powder.

EPSTELL is supplied in Blister pack (Opaque PVDC coated PVC film & Aluminium foil) of 1 x 10, 2 x 10 and 10 x 10 capsules.

Not all pack sizes may be marketed.

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