

Package leaflet: Information for the user

TRADOREC XL® 100 mg, 200 mg, & 300 mg prolonged release tablets 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tradorec XL is and what it is used for
2. What you need to know before you take Tradorec XL
3. How to take Tradorec XL
4. Possible side effects
5. How to store Tradorec XL
6. Contents of the pack and other information

1. What Tradorec XL is and what it is used for.

This medicine is used to treat moderate to severe pain in adults and children over 12 years. It belongs to a group of painkiller medicines called opiate analgesics.

2. What you need to know before you take Tradorec XL

Do not take this medicine:

- If you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6).
- If you are taking linezolid (an antibiotic used to treat severe bacterial infections such as MRSA)
- In acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions).
- If you are taking, or have taken in the last two weeks, MAOIs (medicines used to treat depression).
- If you are suffering from severe liver disease or severe kidney disease.
- If you are suffering from epilepsy, not adequately controlled by treatment.
- If you are breastfeeding, in the case of long-term treatment.

If you are not sure, it is important to ask your doctor or pharmacist for advice.

Warning and precautions

Talk to your doctor or pharmacist or nurse before taking this medicine.

Tell your doctor if you are addicted to another drug, are being treated for withdrawal from another drug or are dependent on another drug. This medicine may cause a psychic or physical dependence (addiction) with long-term use. In patients with a tendency to become addicted to drugs, this medicine should only be used for very short periods and 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 taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Sleep-related breathing disorders

Tradorec XL 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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tradorec XL: 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.

Talk to your doctor before taking this medicine if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tradorec XL').

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

This medicine should be used with caution in the case of:

- reduced consciousness
- brain trauma or any brain disorder such as infection or tumour
- state of shock (cold sweat may be a sign of it)
- breathing difficulties
- a history of epileptic seizures
- kidney or liver disorders
- an increase in normal brain pressure causing symptoms such as headache and vomiting (increased intracranial pressure)
- diabetes

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).

If you are not sure, do not hesitate to consult your doctor or pharmacist for advice.

Children and adolescents

The use of this medicine is not recommended in children under 12 years of age.

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.

Other medicines and Tradorec XL:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines as they may interact with your medicine..

- Carbamazepine (used for the treatment of epilepsy)
- Buprenorphine, nalbuphine, pentazocine (other painkillers)

- Alcohol,
- Naltrexone (used for alcohol or drug abuse).

This medicine may cause seizures at therapeutic doses and in particular when taking high doses and in combination with other medicines including:

- bupropion (used to help stopping smoking)
- mefloquine (a treatment for malaria)

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 this medicine at the same time. Your doctor will tell you whether this medicine is suitable for you.

- if you are taking certain antidepressants. This medicine may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').

This medicine may also interact with the following medicines:

- morphine-like drugs such as cough medicines or substitution treatments such as methadone
- other painkillers
- warfarin (a blood thinner)
- benzodiazepines and other treatments for anxiety
- some treatments for high blood pressure
- antihistamines (for allergies) that cause sleepiness
- thalidomide (for certain cancers and skin conditions)
- barbiturates (sleeping pills)
- neuroleptics, phenothiazine, butyrophenine (to treat mental illness)
- baclophen (a muscle relaxant)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tradorec XL with food and drink and alcohol

Drinking alcohol is not recommended during treatment.

Pregnancy and breast-feeding and fertility

This medicine should not be taken during pregnancy unless absolutely necessary.

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.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine may cause drowsiness. Do not drive or do other activities where you need to be alert (for example using any tools or machines), until you know how the medication affects you. Do not take with alcohol or drugs that make you sleepy.

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.

3. How to take Tradorec XL

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.

Adults and children over 12 years of age – the usual starting dose is 100 mg, once daily. The usual dose after this is 200 mg, once daily. If there is not enough pain relief, the maximum dose is up to 300 or 400 mg, once daily.

Elderly patients (up to 75 years of age) – no dose adjustment is needed.

Elderly patients (above 75 years of age)

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

These are oral tablets. Swallow the tablets whole with a glass of water, preferably in the evening. This medicine may be taken with food or drink. Do not chew or crush them.

These tablets should be taken once every 24 hours.

Strictly follow your doctor's advice at all times.

If you take more Tradorec XL than you should

Contact your doctor immediately.

If you forget to take this medicine

Do not take a double dose to make up for a forgotten tablet.

if you stop taking this medicine

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).

Rarely when some people stop taking this medicine after long-term use, they get withdrawal symptoms. They may feel agitated, anxious, nervous or shaky. They may become over-active

and have difficulty sleeping. These effects usually disappear in a few days. Tell your doctor if this happens to you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects

If you notice any of these symptoms, **stop taking the tablets and consult your doctor straight away.**

- fits (convulsions),
- breathing difficulties,
- rash or allergic reaction of any kind

The following side effects have also been reported:

Very common : may affect more than 1 in 10 people

- feeling sick (nausea),
- dizziness.

Common : may affect up to 1 in 10 people

- constipation,
- sweating,
- dry mouth,
- headache,
- vomiting.
- fatigue
- drowsiness

Uncommon : may affect up to 1 in 100 people

- gastrointestinal irritation (a feeling of pressure in the stomach and wind),
- cardiac and vascular problems (increased heart rate, low blood pressure on standing, feeling unwell with drop in blood pressure),
- skin reactions (itching, rash, hives).

Rare : may affect up to 1 in 1,000 people

- muscle weakness,
- changes in appetite,
- feelings of numbness, itch or pins and needles, tremors,
- slow heart rate or breathing,
- increase in blood pressure,
- blurred vision,
- difficulty in passing urine,
- mood changes (such as feeling unusually happy),
- changes in activity (such as being less active), and changes in thought,
- hallucinations (seeing or hearing things),
- confusion,

- trouble with sleep, nightmares,
- allergic reactions,
- worsening of asthma,
- Drug dependence (become addicted or reliant on this medicine) may occur.
- When treatment is stopped abruptly, signs of withdrawal may appear (see Section 3. 'If you stop taking this medicine')
- epileptic fits,
- in a few isolated cases increases in liver enzymes,
- constriction of the pupil (miosis)
- confused thinking and reduced awareness (delirium)
- anxiety

Not Known: Cannot be estimated from the available data

- Low levels of blood sugar
- Hiccups
- 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) (see section 2 'What you need to know before you take Tradorec XL').

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tradorec XL

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 box. The expiry date refers to the last day of that month.

Blister packs: Do not store above 30°C.

HDPE Bottles: 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 Tradorec XL contains

- The active substance in this medicine is tramadol hydrochloride 100 mg, 200 mg and 300 mg as prolonged released tablets
- The other ingredients are:
polyvinyl acetate, povidone, sodium lauryl sulphate and silica, xanthan gum, hydrogenated vegetable oil (from cotton seed), magnesium stearate (vegetable origin), silica colloidal anhydrous, hydroxypropyl distarch phosphate (E1442).

What Tradorec XL looks like and contents of the pack

This medicine is presented as white to off-white, plain, bevelled edge, round, biconvex prolonged release tablets in the following pack sizes:

PVC/PVDC blisters with Aluminium backing foil (containing 5, 10, 15, 20, 30, 50, 60 or 100 prolonged-release tablets) or

PVC/PE/PCTFE blisters with Aluminium backing foil (containing 5, 10, 15, 30, 60 or 100 prolonged-release tablets) or

HDPE Bottles containing 100 prolonged-release tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Endo Ventures Limited

First Floor

Minerva House

Simmonscourt Road

Ballsbridge

Dublin 4

IRELAND

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