Package Leaflet: Information for the User

Xymel 50mg Capsules

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 Xymel is and what it is used for

Xymel Capsules contain the active ingredient tramadol hydrochloride. Xymel belongs to a group of pain-killing medicines known as opioid analgesics. Xymel Capsules work by acting on certain cells in the spinal cord and brain (the central nervous system).
Xymel Capsules are used for the treatment of moderate to severe pain.

2. What you need to know before you take Xymel

Do not take Xymel
- if you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6)
- in acute poisoning with alcohol, sleeping pills, pain relievers 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 Xymel (see "Other medicines and Xymel")
- if you are an epileptic and your fits are not adequately controlled by treatment
- as a substitute in drug withdrawal.

Warnings and precautions

Talk to your doctor before taking Xymel
- 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.

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).

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.

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

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.

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

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

The pain-relieving effect of Xymel 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 Xymel, and which dose.

The risk of side effects increases:
- if you are taking tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Xymel. 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 of having a fit may increase if you take Xymel at the same time. Your doctor will tell you whether Xymel is suitable for you.
- if you are taking certain antidepressants. Xymel 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.
- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Xymel. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Concomitant use of Xymel 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 Xymel 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.

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

Pregnancy, breast-feeding and fertility

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. There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Xymel Capsules 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. Tramadol is excreted into breast milk. For this reason, you should not take Xymel Capsules more than once during breast-feeding, or alternatively, if you take Xymel Capsules more than once, you should stop breast-feeding. Based on human experience tramadol is suggested not to influence female or male fertility.

Driving and using machines
Xymel Capsules 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.

Xymel contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Xymel

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 more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

Unless otherwise prescribed by your doctor, the recommended dose is:

Adults and adolescents over 12 years of age
One or two capsules (equivalent to 50mg – 100mg tramadol hydrochloride).
Depending on the pain, the effect lasts for about 4–8 hours.
Your doctor may prescribe a different, more appropriate dosage of Xymel if necessary.

Use in children
Xymel Capsules are 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 Xymel capsules. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Method of administration
Xymel Capsules are for oral use.
Always swallow Xymel Capsules whole, not divided or chewed, with sufficient liquid. You may take Xymel on an empty stomach or with meals.

How long should you take Xymel Capsules
You should not take Xymel 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 Xymel Capsules and at what dose.

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

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

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

If you stop taking Xymel
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 Xymel Capsules 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 Xymel is stopped. However, on rare occasions, people who have been taking Xymel Capsules 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 Xymel Capsules, 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.

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.
The most common side effects during treatment with Xymel are nausea and dizziness, which occur in more than 1 in 10 people.

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

Common: may affect up to 1 in 10 people
- Headaches, drowsiness
- Fatigue
- Constipation, dry mouth, being sick (vomiting)
- Sweating (hyperhidrosis)

Uncommon: may affect up to 1 in 100 people
- 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.
- Urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- Skin reactions (e.g. itching, rash)

Rare: may affect up to 1 in 1,000 people
- Allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases.
- Slow heartbeat
- Increase in blood pressure
- Abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- 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.
- Changes in appetite
- Hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- Psychological complaints may appear after treatment with Xymel Capsules. 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 decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement).
- Drug dependence may occur. When treatment is stopped abruptly, signs of withdrawal may appear (see "If you stop taking Xymel").
- Blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupils (miosis).
- Slow breathing, shortness of breath (dyspnoea)
- Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- Weak muscles
- Passing urine with difficulty or pain, passing less urine than normal (dysuria).

Very rare: may affect up to 1 in 10,000 people
- Hepatic enzyme increased

Not known: frequency cannot be estimated from the available data
- decrease in blood sugar level

Reportingofsideeffects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xymel
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 carton and blister strip after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original package. Keep blister in the outer carton.

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 Xymel contains
The active substance is 50 mg **Tramadol hydrochloride**.
The other ingredients are
Microcrystalline cellulose, polyvidone K30, lactose monohydrate, sodium starch glycollate, magnesium stearate. The capsule shells contain titanium dioxide (E171), gelatin, indigotine (E132), erythrosine (E127) and yellow iron oxide (E172). The printing ink contains shellac, black iron oxide (E172) and propylene glycol.

What Xymel looks like and contents of the pack
Xymel 50 mg capsules are green and yellow, size 2, hard gelatin capsules, printed 'TRA 50' and containing white granules.

Xymel 50 mg capsules are available in packs containing 30, 50, 100, 250 and 500 capsules.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer
Clonmel Healthcare Ltd, Clonmel, Ireland.

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