Package Leaflet: Information for the user

Xymel SR 100 mg Prolonged Release Tablets

Active substance: Tramadol Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Xymel SR is and what it is used for

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

2. Before you take Xymel SR

DO NOT TAKE Xymel SR if you:
- are allergic (hypersensitive) to the active substance tramadol hydrochloride or any of the other ingredients of Xymel SR (see section 6, "further information" at the end of this leaflet)
- are intoxicated with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- are also taking monoamine oxidase (MAO) inhibitors (medicines used to treat depression)
- have taken MAO inhibitors within two weeks of when you will start taking Xymel SR
- are an epileptic and your fits are not adequately controlled by treatment
- have severe liver disease
- have severe kidney disease.

Do NOT take Xymel SR as a substitute in drug withdrawal.

Take special care with Xymel SR
You should tell your doctor if you:
- suffer from epilepsy or are at risk of seizures. Normal doses of Xymel SR can increase seizures (fits). Higher doses of Xymel SR can increase the risk of seizures. The risk of

seizures is also higher when Xymel SR are taken with other medicines (see "Taking other medicines")
- have a head injury
- experience pressure inside your skull higher than normal. This can happen after a head injury or can be due to a brain disease such as brain tumour.
- are in shock (signs of shock include cold sweats)
- have difficulty breathing

Drug dependence

Xymel SR can cause drug dependence. Dependence is when you need increasing doses to get the same effect after taking Xymel SR for a long time.
If your doctor thinks that you are at risk of developing dependence, he will treat you with Xymel SR for short periods. Your doctor will also regularly check if you need to continue taking Xymel SR.
Take special care if you are dependent on opioids. Xymel SR is not suitable as a substitute or replacement treatment. It will not help with the symptoms of withdrawal from morphine.

Taking other medicines:

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

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

The effect of Xymel SR may be greater if:
- you are also taking other medicines which act on your central nervous system
- you are drinking alcohol (see also "Driving and Using Machines").

The painkilling effect of Xymel SR may be reduced and shortened if:
- you also take carbamazepine (a medicine for epilepsy and mental disorders).

You should not take Xymel SR 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 of having a fit may increase if you take Xymel SR at the same time. Your doctor will tell you whether Xymel SR is suitable for you.
- if you are taking certain antidepressants. Xymel SR 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 develop these symptoms, you should **contact your doctor immediately**. Your doctor may tell you to stop taking Xymel SR. These symptoms will get better quickly if you stop taking these medicines.

You should take care if you are also taking blood-thinning drugs (e.g. warfarin). Xymel SR 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 vomiting (being sick), you may need to take more Xymel SR. Your doctor will decide your dose. Ondansetron is often used during cancer treatment (chemotherapy) or before and after an operation.

Cimetidine, a medicine used to treat stomach ulcers, may increase the effects of tramadol.

Taking Xymel SR with food and drink:
Xymel SR may be taken with or without food. The effect of Xymel SR may be greater if you drink alcohol.

Pregnancy and breast-feeding:
Ask your doctor for advice before taking any medicine.

Pregnancy
There is little information on the safety of Xymel SR 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 Xymel SR if your doctor tells you to. Your doctor will decide if you should take Xymel SR.

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

Breast-feeding
Very small amounts of tramadol may pass through your breast-milk to your infant. Don't take more than a single dose of Xymel SR while breast-feeding your baby. You can continue breast feeding for you have taken only a dose of Xymel SR.

Driving and using machines:
Xymel SR may cause drowsiness. This may be made worse by alcohol or other medicines. If you have these symptoms you must not drive or use machines.

3. How to take Xymel SR

Always take Xymel SR exactly as your doctor has told you. You should check with your doctor 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.

Your doctor will treat you with Xymel SR for short periods with regular breaks. This will minimise the risk of you developing dependence (see "Take special care with Xymel SR").

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

Adults and children over 12 years of age:
One Xymel SR Tablet twice daily preferably in the morning and evening. A total daily dose of 400 mg tramadol should not be exceeded without medical advice.

Children:
Xymel SR is 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.

Patients with kidney or liver problems:
Patients with severe liver and/or kidney insufficiency should not take Xymel SR. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval. The effectiveness of Xymel SR is not reduced if you have kidney problems and need blood filtration (dialysis).
Tramadol capsules may be more appropriate.

Swallow the tablets whole with plenty of liquid, preferably in the morning and evening.
DO NOT CRUSH OR CHEW THE TABLETS. Xymel SR may be taken with or without food.

How long should you take Xymel SR
Xymel SR should not be administered longer than necessary. If long-term treatment of pain is required, your doctor should assess the need for continued treatment with these tablets at regular intervals. Do not change the prescribed dosage by yourself. If you think that the effect of Xymel SR is too weak or too strong, talk to your doctor or pharmacist. If you have been taking these tablets for a long time, you should not stop taking them without consulting with your doctor first.

If you take more Xymel SR than you should:
Contact your doctor or pharmacist or telephone your nearest casualty department immediately. Remember to take the pack and any remaining tablets with you.

Your doctor will treat the symptoms of tramadol overdose. Symptoms of overdose include:

- constriction of the pupil of the eye (miosis)
- being sick (vomiting)
- serious heart and circulation problems (cardiovascular collapse)
- a calming effect (sedation) and loss of consciousness (coma)
- fits (seizures)
- slow or shallow breathing (respiratory depression).

If you forget to take Xymel SR:
If you forget to take a dose of Xymel SR, just take the next dose at the usual time. DO NOT take a double dose to make up for the missed one.

If you stop using Xymel SR:
If you interrupt or finish treatment with Xymel SR 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 SR is stopped. However, on rare occasions, people who have been taking Xymel SR tablets 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 noise in the ears (tinnitus). If you experience any of these complaints after stopping Xymel SR, please consult your doctor.

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

4. Possible side effects

Like all medicines, Xymel SR can cause side effects, although not everyone gets them.
Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment
Stop taking the medicine and contact your doctor immediately if you get symptoms of a severe allergic reaction (angioedema) such as:

- swollen face, extremities, tongue, voice box or throat, difficulty swallowing
- hives (urticaria)
- difficulty breathing

The evaluation of the side effects is based on the following frequencies:
Very common (affects more than 1 user in 10):

- feeling sick (nausea)
- dizziness

Common (affects 1 to 10 users in 100):

- being sick (vomiting)
- constipation
- dry mouth
- headache
- sweating
- fatigue.

Uncommon (affects 1 to 10 users in 1,000):

- retching
- gastrointestinal irritation (a feeling of pressure in the stomach, bloating), diarrhoea
- cardiovascular regulation including feeling your heartbeat (palpitations), rapid heartbeat (tachycardia), feeling dizzy or faint on standing (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 (pruritis)
    - rash
    - hives (urticaria)

Rare (affects 1 to 10 users in 10,000):

- Changes in appetite
- Slow heat beat (bradycardia)
- Increase in blood pressure
- Slow or shallow breathing (respiratory depression). You may develop respiratory depression if:
    - You take more than the recommended dose (see **section 2** "Taking other medicines") and

- You take other substances which depress the central nervous system (see "Taking other medicines")

– Fits similar to epilepsy (epileptiform convulsions). These are more likely to occur:
  - after high doses of Xymel SR or
  - after taking drugs which cause fits or make fits more likely. For example, antidepressants or anti-psychotic medicines (see "Taking other medicines").
– Pins and needles (paraesthesia)
– Shaking (tremor)
– Mental (psychological) side effects may occur following administration of tramadol. These vary in intensity and type depending on:
– your personality
– how long you take Xymel SR for.
– These include
  - changes in mood -usually happiness (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 sensory perception) 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
– Bad dreams (nightmares)
– Blurred vision
– Effects on the nervous system
– Difficulty / inability in passing urine
– Allergic (hypersensitivity) reactions including:
- Shortness of breath (dyspnoea)
- Constriction of the lower airways causing difficulties in breathing (bronchospasm)
- Wheezing
- Angioedema/ severe allergic reactions

Very rare (affects less than 1 user in 10,000):
– Drug dependence
– Abuse and withdrawal reactions. Symptoms of such withdrawal reactions may include restlessness (agitation), feeling uneasy (anxiety), nervousness, difficulty sleeping (insomnia), increased movement, such as muscle twitching or tics (hyperkinesia), shaking (tremor), symptoms affecting the stomach or intestines (gastrointestinal symptoms).

Not known (frequency cannot be estimated from the available data):
– Worsening of asthma
– Increase in liver enzyme values
– Decrease in blood sugar level

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, tell your doctor or pharmacist.

5. How to store Xymel SR

Store in the original package in order to protect from light.

Keep out of reach and sight of children.

Do not use Xymel SR after the expiry date stated on the carton and blister strip. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Xymel SR contains:
The active substance is tramadol hydrochloride. Each tablet contains 100 mg tramadol hydrochloride in a prolonged release formulation. The tablets also contain, hypromellose 15000, microcrystalline cellulose, povidone, silica colloidal anhydrous and magnesium stearate. The film-coating contains macrogol 6000, hypromellose 5, talc, polyacrylate dispersion 30% and the following colour: titanium dioxide (E171).

What Xymel SR looks like and contents of the pack:
Xymel SR are white, round, biconvex film-coated tablets. Xymel SR are available in blister packs of 10, 15, 20, 30, 40, 45, 50, 60, 100 and 100 x 1 (unit dose) tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder:
Clonmel Healthcare Ltd, Clonmel, Ireland.

Manufacturers:
Clonmel Healthcare Ltd, Clonmel, Ireland.

Lannacher Heilmittel Ges. m.b.H., 8502 Lannach, Austria.

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