

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zydol® 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 (section 4).

In this leaflet:

- What Zydol is and what it is used for
- What you need to know before you take Zydol
- How to take Zydol
- Possible side effects
- How to store Zydol
- Contents of the pack and other information

1. What Zydol is and what it is used for

The full name of your medicine is 'Zydol 50mg Capsules'. It is referred to as 'Zydol' in the rest of this leaflet.

Tramadol - the active substance in Zydol - is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Zydol is used for the treatment of moderate to severe pain.

2. What you need to know before you take Zydol

Do not take Zydol

- 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 Zydol (see "Other medicines and Zydol")
- 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 Zydol

- 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 (400mg).

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

Other medicines and Zydol

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

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

The pain-relieving effect of Zydol 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 Zydol, 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 Zydol. 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 Zydol at the same time. Your doctor will tell you whether Zydol is suitable for you.
- if you are taking certain antidepressants Zydol 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 take coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Zydol. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Zydol with food and alcohol

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

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 Zydol 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. Small amounts of tramadol are excreted into breast milk. After a single dose it is usually not necessary to interrupt breast-feeding.

Based on human experience tramadol is suggested not to influence female or male fertility.

Driving and using machines

Zydol 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 Zydol

Always take this medicine exactly as your doctor has told you. You should 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 400mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

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

Adults and adolescents from the age of 12 years

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 Zydol if necessary.

Children

Zydol 50mg 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 Zydol. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Zydol?

Zydol capsules are for oral use.

Always swallow Zydol capsules whole, not divided or chewed, with sufficient liquid. You may take Zydol on an empty stomach or with meals.

How long should you take Zydol?

You should not take Zydol 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 Zydol capsules and at what dose.

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

If you take more Zydol 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 Zydol 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 Zydol

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

If you stop taking Zydol

If you interrupt or finish treatment with Zydol 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 Zydol is stopped. However, on rare occasions, people who have been taking Zydol 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 Zydol, 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 Zydol are nausea and dizziness, which occur in more than 1 in 10 people.

Very common: may affect more than 1 in 10 people

- dizziness
- feeling sick (nausea)

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 Zydol. 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 judgment)
- drug dependence may occur. If Zydol is taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly, signs of withdrawal may appear (see "If you stop taking Zydol")
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (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

Reporting of side effects

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 Zydol

- Do not use Zydol capsules after the expiry date (EXP) which is stated on the carton and the blister.
- Store in the original container. Do not store above 25°C.
- Keep out of the sight and reach of children.
- If you have any unused/left-over capsules, please return these to your pharmacist for safe disposal.
- If your capsules appear to be discoloured or show any other signs of deterioration, please return these to your pharmacist who will advise you.
- 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. Contents of the pack and other information

What Zydol contains

The active substance is tramadol hydrochloride.

Each capsule contains 50mg tramadol hydrochloride.

The other ingredients are: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal anhydrous silica.

Capsule shell contains: gelatine, sodium laurilsulfate, yellow iron oxide (E172) and titanium dioxide (E171).

What Zydol looks like and contents of the pack

The capsules are yellow/yellow shiny hard gelatin capsules.

Zydol 50mg capsules are available in packs of 100.

Manufacturer

Grünenthal GmbH, Zieglerstr. 6, D-52078 Aachen, Germany.

Procured from within the EU by the PPA holder:

Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by:

Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

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