

## Package leaflet: Information for the patient

### **Zydol® XL 150 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets**

Tramadol hydrochloride

**This medicine contains tramadol which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**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 **Zydol XL** tablets are and what they are used for
2. What you need to know before you take **Zydol XL** tablets
3. How to take **Zydol XL** tablets
4. Possible side effects
5. How to store **Zydol XL** tablets
6. Contents of the pack and other information

#### **1. What *Zydol XL* tablets are and what they are used for**

These tablets have been prescribed for you to relieve moderate to severe pain over a period of 24 hours. They contain the active ingredient tramadol which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed for you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking **Zydol XL** tablets suddenly. Your prescriber should have explained how long you will be taking them for and when it is appropriate to stop, how to do this safely.

These tablets are only for use in adults and adolescents over 12 years of age.

#### **2. What you need to know before you take *Zydol XL* tablets**

##### **Do not take *Zydol XL* tablets:**

- if you are allergic to tramadol or any of the other ingredients of these tablets (listed in section 6 of this leaflet);
- if you have drunk too much alcohol, or taken more than the recommended dose of sleeping tablets, painkillers or psychotropic medicines (used to treat psychiatric or mental disorders);
- if you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or if you have taken this type of medicine in the last two weeks;
- to treat withdrawal symptoms that may occur when you stop taking another strong painkiller;
- if you have a rare hereditary problem of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

## Warnings and precautions

Talk to your prescriber before taking these tablets if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs;
- 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 this medicine to get the same level of pain relief. This may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever;
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and **Zydol XL** tablets).
- suffer from, or have ever suffered from epilepsy, seizures, fits or convulsions;
- know you are suffering from a brain injury or tumour, or you have a head injury, severe headache or feel sick, as this may indicate that the pressure in your skull is increased. This is because the tablets may make symptoms worse or hide the extent of any head injury;
- have severe liver or kidney problems;
- are suffering from shock (this may make you suddenly feel very lightheaded, faint, cold or clammy and look pale);
- are feeling very lightheaded or faint;
- have a condition where you breathe more slowly and weakly than usual (respiratory depression);
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- are currently suffering from constipation

Taking this medicine 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 this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. 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 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.

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').

## Sleep-related breathing disorders

**Zydol XL** tablets 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.

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.

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while taking **Zydol XL** tablets: 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

##### Use in children after an operation

If your child is given these tablets after an operation they will be monitored closely to ensure that they are not breathing more slowly or weakly than usual (respiratory depression). If you notice that your child is breathing slowly or weakly after an operation, tell their doctor or nurse **immediately**.

##### Use in children with breathing problems

Tramadol is not recommended in children with breathing problems, since any side effects of tramadol may be worse in these children.

#### **Other medicines and Zydol XL tablets**

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

Using **Zydol XL** tablets at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:

- other medicines used to treat pain known as opioids (such as codeine or morphine);
- medicines used to treat anxiety;
- medicines used to make you feel sleepy (such as benzodiazepines);
- medicines used to treat psychiatric or mental disorders (such as phenothiazines);
- medicines used to treat depression, including a type of medicine known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not use **Zydol XL** tablets if you are currently taking this type of medicine, or have taken this medicine in the last two weeks (see section 2 'Do not take...').

Because of this, your doctor will only prescribe **Zydol XL** tablets where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor **immediately**.

If you are taking any of the following, your risk of experiencing seizures, fits or convulsions may be increased whilst you are taking **Zydol XL** tablets:

- medicines used to treat depression known as selective serotonin reuptake inhibitors, or SSRIs (such as citalopram, fluoxetine or sertraline);
- medicines used to treat depression known as selective norepinephrine reuptake inhibitors, or SNRIs (such as venlafaxine or duloxetine);
- tricyclic antidepressants (such as amitriptyline, clomipramine or imipramine);
- monoamine oxidase inhibitors, or MAOIs (such as tranylcypromine, phenelzine or isocarboxazid);
- medicines used to treat serious psychiatric disorders (antipsychotics);
- a medicine used to help stop smoking known as bupropion;
- a medicine used to treat depression, obsessive compulsive disorder and anxiety, known as mirtazapine;
- tetrahydrocannabinol or THC (cannabis).

The risk of side effects increases if you are taking certain antidepressants. **Zydol XL** tablets may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').

Tell your doctor or pharmacist if you are taking:

- carbamazepine to treat seizures, fits or convulsions and certain pain conditions;
- cimetidine, a medicine used to treat stomach ulcers;
- ritonavir, a medicine used to treat HIV;
- digoxin, a medicine used to treat heart failure or an irregular heart beat;
- other strong analgesics or 'painkillers' (such as buprenorphine, nalbuphine and pentazocine);
- certain medicines to prevent your blood clotting or to help thin your blood (known as coumarin anticoagulants, for example warfarin);
- ondansetron, a medicine used to treat nausea and vomiting.

#### **Zydol XL tablets and alcohol**

Drinking alcohol whilst taking **Zydol XL** tablets may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended that you do not drink alcohol while you are taking **Zydol XL** tablets.

#### **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 these tablets.

#### **Pregnancy**

Do not take these tablets if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby. Depending on the dose and duration of treatment with tramadol, slow and shallow breathing (respiratory depression) may occur in the newborn infant.

If you use these tablets during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated. Withdrawal symptoms may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

#### **Breast-feeding**

Do not take these tablets while you are breast-feeding as tramadol passes into breast milk and will affect your baby.

### **Driving and using machines**

These tablets may cause a number of side effects such as drowsiness, blurred vision and dizziness which could affect your ability to drive or use machinery (see section 4 'Possible side effects' for a full list of side effects). These are usually most noticeable when you first start taking the tablets, or when changing to a higher dose.

- 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.

### **Zydol XL tablets contain lactose**

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

### **3. How to take Zydol XL tablets**

Always take these tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The label on your medicine will tell you how many tablets to take and how often. 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 prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

### **Adults and adolescents over 12 years of age**

The usual starting dose is one 150 mg tablet once a day. However, your doctor will prescribe the dose required to treat your pain. Do not exceed the dose recommended by your doctor. If you find that you are still in pain whilst taking these tablets discuss this with your doctor.

Swallow your tablets whole with water. **Do not crush, dissolve or chew them.**

**Zydol XL tablets are designed to work properly over 24 hours when swallowed whole. If a tablet is broken, crushed, dissolved or chewed, the entire 24-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.**

You should take your tablets at the same time every day. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock the next morning.

### **Elderly patients**

In elderly patients (above 75 years) it may take longer for tramadol to leave the body. If this applies to you, your doctor may recommend prolonging the interval between doses.

### **Severe liver or kidney disease (insufficiency)/ dialysis patients**

In patients with severe liver and/or kidney insufficiency it may take longer for tramadol to leave the body. If this applies to you, your doctor may recommend prolonging the interval between doses.

#### **Children under 12 years of age**

Children under 12 years of age should not take the tablets.

#### **If you take more *Zydol XL* tablets than you should or if someone accidentally swallows your tablets**

Call your doctor or local hospital **immediately**. People who have taken an overdose may feel very sleepy, sick or dizzy. They may have seizures, fits or convulsions. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you.

#### **If you forget to take *Zydol XL* tablets**

If you remember within 10 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at your normal time. If you are more than 10 hours late, please call your doctor for advice. Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking *Zydol XL* tablets**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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

#### **4. Possible side effects**

Like all medicines, these tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Tell your doctor **immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 1,000 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and *Zydol XL* tablets'). Tell your doctor **immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

In patients treated with *Zydol XL* tablets the following other side effects have been reported:

##### **Very common** (may affect more than 1 in 10 people)

- feeling sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem);
- dizziness.

##### **Common** (may affect up to 1 in 10 people)

- drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days.);
- vomiting (being sick), dry mouth;
- excessive sweating.

**Uncommon** (may affect up to 1 in 100 people)

- headache;
- a fast heartbeat, feeling your heart beat (palpitations);
- feeling faint, especially on standing up, low blood pressure, circulation failure;
- retching;
- a raised, itchy rash (hives), swelling or puffiness of the skin;
- constipation;
- abdominal pain or discomfort;
- withdrawal symptoms when you stop taking these tablets, known as drug withdrawal syndrome (see section 'Drug Withdrawal').

**Rare** (may affect up to 1 in 1,000 people)

- signs of an allergic reaction, including wheeziness, difficulty breathing, swelling of the eyelids, face or lips, rash or itching (see above);
- tingling, pricking or numbness of the skin, impaired judgement, agitation, changes in the way you perceive things around you (sensory disturbance);
- blurred vision;
- seeing or hearing things that are not real (hallucinations);
- nightmares;
- mood changes, unpleasant or uncomfortable moods or a feeling of extreme happiness;
- changes in activity levels;
- confusion;
- problems with recognition, changes in thinking, memory and behaviour;
- seizures, fits or convulsions;
- high blood pressure;
- shortness of breath, difficulty in breathing or wheezing;
- worsening of asthma;
- decreased appetite;
- diarrhoea;
- difficulty in passing urine, pain when urinating;
- muscle weakness;
- flushing of the skin;
- slow heartbeat.

**Very rare** (may affect up to 1 in 10,000 people)

- a worsening in liver function tests (seen in a blood test).

**Not known** (frequency cannot be estimated from the available data)

- dependence and addiction (see section 'How do I know if I am addicted?');
- development of a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- a need to take increasingly higher doses to obtain the same level of pain relief (drug tolerance);
- 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 **Zydol XL** tablets);

- increased sensitivity to pain;
- weakness or lack of energy;
- decrease in blood sugar level;
- hiccups.

Long term use of **Zydol XL** tablets during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

You may see the remains of the tablets in your faeces. This should not affect how the tablets work.

#### Drug Withdrawal

When you stop taking **Zydol XL** tablets you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

#### **How do I know if I am addicted?**

If you notice any of the following signs whilst taking **Zydol XL**, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

#### **Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This includes any 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store **Zydol XL** tablets**

Keep these tablets out of the sight and reach of children.

Do not take these tablets after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Do not store your tablets above 30°C.

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 **Zydol XL** tablets contain**

The active ingredient is tramadol hydrochloride. Each tablet contains 150 mg, 200 mg, 300 mg or 400 mg of tramadol hydrochloride.

The other ingredients are hydrogenated vegetable oil, talc, magnesium stearate, lactose monohydrate, macrogol, hypromellose (E464), titanium dioxide (E171).

**What Zydol XL tablets look like and the contents of the pack**

They are white, film-coated, oval shaped tablets marked T followed by the strength (e.g. 150, 200, 300 or 400). The 150 mg strength tablets are approximately 13 mm in length, the 200 mg strength tablets are approximately 15 mm in length, the 300 mg strength tablets are approximately 17 mm in length and the 400 mg strength tablets are approximately 19 mm in length.

In each box there are 30 tablets.

**Marketing Authorisation Holder and Manufacturer**

The tablets are made by Grünenthal GmbH, Zieglerstr. 6, 52078 Aachen, Germany for the marketing authorisation holder Napp Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

**Zydol XL** 150 mg, 200 mg, 300 mg and 400 mg tablets are supplied by Grünenthal Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley Park East, Uxbridge, Middlesex, UB11 1BD, UK.

This leaflet is also available in large print, Braille or as an audio CD.

To request a copy, please call the RNIB Medicine Information line (free of charge) on: 0800 198 5000

You will need to give details of the product name and reference number. These are as follows:

Product name: Zydol XL prolonged release tablets

Reference number: 16950/0089

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**Zydol<sup>®</sup> XL** 150 mg, 200 mg, 300 mg, and 400 mg tablets are protected by European Patent (UK) No. 0699436 and 0654263.

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