

# Zydol® SR

## 100 mg, 150 mg and 200 mg prolonged release tablets

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 any further questions, ask your doctor or your 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

### In this leaflet:

1. What Zydol SR is and what it is used for
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### 1. WHAT Zydol SR IS AND WHAT IT IS USED FOR

Tramadol - the active substance in Zydol SR - 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 SR is used for the treatment of moderate to severe pain.

### 2. BEFORE YOU TAKE Zydol SR

#### Do not take Zydol SR,

- if you are allergic (hypersensitive) to tramadol or any of the other ingredients of Zydol SR;
- 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 SR (see "Taking other medicines");
- if you are an epileptic and your fits are not adequately controlled by treatment;
- as a substitute in drug withdrawal.

#### Take special care with Zydol SR,

- 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;

In such cases please consult your doctor before taking the medicine. 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).

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

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Zydol SR should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of Zydol SR may be reduced and the length of time it acts may be shortened, if you take medicines which contain

- carbamazepine (for epileptic fits);
- pentazocine, nalbuphine or buprenorphine (pain killers);
- ondansetron (prevents nausea).

Your doctor will tell you whether you should take Zydol SR, and what dose. The risk of side effects increases,

- if you take tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Zydol SR. 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. The risk having a fit may increase if you take Zydol SR at the same time. Your doctor will tell you whether Zydol SR is suitable for you.
- if you are taking selective serotonin reuptake inhibitors (often referred to as SSRIs) or MAO inhibitors (for the treatment of depression). Zydol SR may interact with these medicines and you may experience symptoms such as confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, or diarrhoea.
- if you take coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Zydol SR. The effect of these medicines on blood clotting may be affected and bleeding may occur.

### Taking Zydol SR with food and drink

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

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Zydol SR 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. On a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

### Driving and using machines

Zydol SR 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, and do not work without a firm hold!

### Important information about some of the ingredients of Zydol SR

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This is because the tablets contain lactose

### 3. HOW TO TAKE Zydol SR

Always take Zydol SR 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.

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

#### Adults and adolescents from the age of 12 years

One Zydol SR 100 mg prolonged-release tablet twice daily (equivalent to 200 mg tramadol hydrochloride per day), preferably in the morning and evening.

One Zydol SR 150 mg prolonged-release tablet twice daily (equivalent to 300 mg tramadol hydrochloride per day), preferably in the morning and evening.

One Zydol SR 200 mg prolonged-release tablet twice daily (equivalent to 400 mg tramadol hydrochloride per day), preferably in the morning and evening.

Your doctor may prescribe a different, more appropriate dosage strength of Zydol SR if necessary.

Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

#### Children

Zydol 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.

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

Patients with severe liver and/or kidney insufficiency should not take Zydol SR. 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 SR?

Zydol SR tablets are for oral use.

Always swallow Zydol SR tablets whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the tablets on an empty stomach or with meals.

#### How long should you take Zydol SR?

You should not take Zydol SR 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 SR tablets and at what dose.

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

#### If you take more Zydol SR 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 SR tablets 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, a fall in blood pressure, a fast heart beat, collapse, unconsciousness, fits and breathing difficulty or shallow breathing.

#### If you forget to take Zydol SR

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

## If you stop taking Zydol SR

If you interrupt or finish treatment with Zydol 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 Zydol SR is stopped. However, on rare occasions, people who have been taking Zydol 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 confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, delusions, paranoia, hallucinations or feeling a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and "ringing" in the ears (tinnitus). If you experience any of these complaints after stopping Zydol 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, Zydol SR can cause side effects, although not everybody gets them.

In case one of the following situations occur, see your doctor straight away:

- allergic reactions e.g. difficulty in breathing, wheezing, swelling of skin (occurs rarely),
- swollen face, tongue and/or throat and/or difficulty to swallow or hives together with difficulties in breathing (occurs rarely),
- shock/sudden circulation failure (occurs rarely).

Usually the frequency of side effects is classified as follows:

- very common (more than 1 out of 10 persons),
- common (more than 1 out of 100 persons),
- uncommon (more than 1 out of 1,000 persons),
- rare (more than 1 out of 10,000 persons)
- very rare (less than 1 out of 10,000 persons).

The most common side effects during treatment with Zydol SR are nausea and dizziness, which occur in more than in 1 out of 10 patients.

### Heart and blood circulation disorders

uncommon: effects on the heart and blood circulation (pounding of the heart, fast heart beat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.

rare: slow heart beat, increase in blood pressure.

### Nervous system disorders

very common: dizziness.

common: headaches, drowsiness.

rare: changes in appetite, abnormal sensations (e.g. itching, tingling, numbness), trembling, slow breathing, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope).

If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.

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.

### Psychiatric disorders

rare: hallucinations, confusion, sleep disorders, anxiety and nightmares.

Psychological complaints may appear after treatment with Zydol SR. 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 being less aware and less able to make decisions, which may lead to errors in judgement.

Dependence may occur.

### Eye disorders

rare: blurred vision.

### Respiratory disorders

rare: shortness of breath (dyspnoea).

Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.

### Stomach and bowel disorders

very common: feeling sick.

common: being sick, constipation, dry mouth.

uncommon: urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea.

### Skin disorders

common: sweating

uncommon: skin reactions (e.g. itching, rash).

### Muscle disorders

rare: weak muscles.

### Liver and biliary disorders

very rare: increase in liver enzyme values.

### Urinary disorders

rare: passing water difficult or painful, less urine than normal.

## General disorders

common: tiredness, weariness, weakness, low energy.

There have been some reports of speech disorders and dilated pupils. If Zydol SR tablets are 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 SR").

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

## 5. HOW TO STORE Zydol SR

Keep out of the reach and sight of children.

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

Do not store above 30°C.

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 Zydol SR contains

#### 100 mg

Each tablet contains 100 mg tramadol hydrochloride.

The other ingredients are:

microcrystalline cellulose, hypromellose, hypromellose, magnesium stearate, colloidal anhydrous silica, lactose monohydrate, macrogol 6000, propylene glycol, talc and titanium dioxide (E171).

#### 150 mg

Each tablet contains 150 mg tramadol hydrochloride.

The other ingredients are:

microcrystalline cellulose, hypromellose, magnesium stearate, colloidal anhydrous silica, lactose monohydrate, macrogol 6000, propylene glycol, talc, titanium dioxide (E171), quinoline yellow lake (E104) and red iron oxide (E172).

#### 200 mg

Each tablet contains 200 mg tramadol hydrochloride.

The other ingredients are:

microcrystalline cellulose, hypromellose, magnesium stearate, colloidal anhydrous silica, lactose monohydrate, macrogol 6000, propylene glycol, talc, titanium dioxide (E171), quinoline yellow lake (E104), red iron oxide (E172) and brown iron oxide (E172).

### What Zydol SR looks like and contents of the pack

Zydol SR 100 mg tablets are white and round and have "T1" and  marked on them.

Zydol SR 150 mg tablets are pale orange and round and have marked "T2" and  marked on them.

Zydol SR 200 mg tablets are slightly brownish orange and round and have marked "T3" and  marked on them.

Zydol SR 100 mg tablets are packed in blisters and are supplied in boxes of 2, 4, 10, 30 and 60 tablets. Zydol SR 150 mg tablets are packed in blisters and are supplied in boxes of 2, 4, 10, 30 and 60 tablets. Zydol SR 200 mg tablets are packed in blisters and are supplied in boxes of 2, 4, 10, 30 and 60 tablets. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Grünenthal Ltd.  
Regus Lakeside House  
1 Furzeground Way  
Stockley Park East

Uxbridge  
Middlesex  
UB11 1BD  
United Kingdom

Manufacturer:  
Grünenthal GmbH  
Zieglerstr. 6  
D-52078  
Germany

### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

# 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Zydol SR 100 mg prolonged-release tablets	PL 21727/003
Zydol SR 150 mg prolonged-release tablets	PL 21727/004
Zydol SR 200 mg prolonged-release tablets	PL 21727/005

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