

Zydol™ SR

tramadol hydrochloride

Consumer Medicine Information

WARNING

Limitations of use

ZYDOL SR should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

ZYDOL SR poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

ZYDOL SR can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting ZYDOL SR and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using ZYDOL SR

Using ZYDOL SR with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using ZYDOL SR.

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about Zydol Sustained Release tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking Zydol SR against the benefits this medicine is expected to have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet.

You may need to read it again.

What Zydol SR is used for

ZYDOL SR is used to relieve severe pain which requires daily, long term treatment. It belongs to a group of medicines called opioid analgesics (pain relievers).

ZYDOL SR tablets are designed to release active medicine gradually over several hours.

Your doctor may have prescribed ZYDOL SR for another reason. Ask your doctor why this medicine has been prescribed for you.

ZYDOL SR is available only on a doctor's prescription.

ZYDOL SR is for use in adults and children over 12 years of age.

It should not be used in children under the age of 12 years or following the removal of tonsils and/or adenoids in people under 18.

Before you use Zydol SR

When you must not use this medicine

Do not take ZYDOL SR if:

- you have an allergy to any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing and swelling of the face (including lips, tongue, throat etc)
- you have an allergy to any other medicines known as opioid analgesics, eg. morphine or codeine
- you have respiratory disease or slow or shallow breathing
- you have taken large amounts of alcohol or other substances which can affect your level of consciousness. Some examples of these substances include sleeping pills, pain

relievers or other psychotropic medicines (medicines that affect mood and emotions)

- you are taking medicine for depression containing a "monoamine oxidase inhibitor" also known as MAOI, or have taken any within the past two weeks. Examples of MAOI-containing medicines are Nardil®, Parnate®
- you have uncontrolled epilepsy or if your epilepsy is not well controlled by treatment
- you are younger than 12 years old or if you are between 12 – 18 years of age and are recovering from an operation to remove your tonsils and/or adenoids.

Do not take ZYDOL SR if the packaging is torn or shows signs of tampering.

Do not take ZYDOL SR if any tablets look damaged or discoloured.

Do not take ZYDOL SR after the expiry date which is printed on the carton box.

If you take this medicine after the expiry date has passed, it may not work as well.

If it is after the expiry date, or the packaging is damaged, return it to your pharmacist for disposal.

Addiction

You can become addicted to ZYDOL SR even if you take it exactly as prescribed. ZYDOL SR may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking ZYDOL SR. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking ZYDOL SR suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to ZYDOL SR may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea

- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Very rarely, some patients have experienced the following withdrawal reactions:

- panic attacks
- severe anxiety
- hallucinations
- tingling or numbness (pins and needles)
- ringing in your ears
- confusion, delusions or paranoia.

ZYDOL SR given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you know you are sensitive to Zydol SR or any of the ingredients listed at the end of this leaflet
- you know you are sensitive to opioids
- you drink alcohol
- you have any health problems including:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - fits or convulsions, or take medicines for epilepsy
 - any condition that may affect how your kidney or liver work
 - any stomach problems
 - a severe headache or feel sick due to a head injury
- you have, or have had, any drug or alcohol dependence problems
- you have galactose intolerance, or lactase deficiency or glucose-galactose malabsorption
- you are pregnant or intend to become pregnant. ZYDOL SR is not recommended for use during pregnancy. ZYDOL SR can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using ZYDOL SR during pregnancy
- you are breast feeding or plan to breast feed. ZYDOL SR is not recommended for use during breast feeding. Talk to your doctor about the risks and benefits of using ZYDOL SR when breast-feeding

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZYDOL SR. These include:

- carbamazepine (eg. Tegretol®)
- coumarin derivatives (eg. Warfarin: some Brand names are Coumadin®, or Marevan®)
- medicine for irregular or rapid heart beat
- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-noradrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- some antibiotics.

These medicines may be affected by ZYDOL SR, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Other interactions not listed above may also occur.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ZYDOL SR.

How to take this medicine

Carefully follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

ZYDOL SR tablets should be swallowed whole with water. They may be taken, before, with, or after food.

ZYDOL SR tablets are only designed to work properly if swallowed whole. The tablets may release all their contents at once if broken, chewed, crushed or dissolved, which can be dangerous and cause serious problems, such as an overdose which may be fatal. Unless stated otherwise, they should be swallowed whole.

How much to take

The recommended dosage of ZYDOL SR is either:

- two ZYDOL SR 50 tablets twice a day (morning and evening)
OR
- one or two ZYDOL SR 100 mg tablet(s) twice a day (morning and evening)
OR
- one ZYDOL SR 150 mg or 200 mg tablet twice a day (morning and evening).

As all patients respond to treatment differently, your doctor may start you on a lower dose.

Do not take more than eight of the 50 mg tablets per day.

Do not take more than four of the 100 mg tablets per day

Do not take more than two of the 150 mg or of the 200 mg tablets per day.

If you are over 75 years of age, you may require a lower daily dose of ZYDOL SR compared to younger adults.

If you forget to take it

If you forget to take one dose, take the dose when you remember. The following dose should be taken after twelve hours, or as prescribed by your doctor.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take it

This differs between individuals depending on how severe your pain is, how you respond to ZYDOL SR, and the cause of your pain. Ask your doctor for advice on how long you need to take ZYDOL SR tablets.

If you take too much (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used ZYDOL SR that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much ZYDOL SR, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If your pain is not as severe and you feel that you do not need to take as many Zydol SR tablets as your doctor prescribed, consult your doctor.

Tell your doctor if your pain is not helped or gets worse. Do not take increased amounts or extra doses without checking with your doctor.

Tell any other doctors, dentists, and pharmacists who treat you, that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they seem to have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

All medicines can cause unwanted effects, and some side-effects have been reported with ZYDOL SR. Most side-effects reported with ZYDOL SR are minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The most common side-effects of ZYDOL SR are:

- dizziness
- sedation, fatigue
- headache
- constipation
- nausea, vomiting
- sweating
- dry mouth.

The following side-effects are less common:

- indigestion
- hiccups
- changes in appetite
- skin reactions
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor
- seizures
- respiratory depression
- improvement of mood
- confusion
- sleep disturbance
- blurred vision
- difficulty in passing urine
- Serotonin Syndrome: signs of this vary and are not specific; they may include sweating, agitation, muscle twitching, spontaneous muscle contraction, tremor, high body temperature. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.
- low blood glucose (hypoglycaemia)

This is not a complete listing.

Occasionally, other side-effects may be experienced.

Tell your doctor immediately if you experience any of the following side-effects, as urgent medical treatment may be required:

- skin rash (red spots or patches), itching hives, skin lumps
- swelling or puffiness of the eyelids, face or lips

- chest tightness, wheezing or pain in the chest
- heart palpitations, faintness or collapse
- hallucinations
- convulsions

Talk to your doctor if you experience any of the following symptoms while taking ZYDOL SR 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).

Adrenal insufficiency is caused by failure of the adrenal glands to produce enough or any of the hormones cortisol and aldosterone.

If you have these symptoms, contact your doctor, who will decide if you need to talk hormone supplement.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Storage and Disposal

Storage

Keep it in the pack until it is time to take them.

If you take Zydol SR out of the pack it may not keep well.

Keep it in a cool dry place where the temperature stays below 30°C. Do not store it in the bathroom or near a sink. Protect from light.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Zydol SR or it passes its expiry date, ask your pharmacist what to do with any Zydol SR that is left over.

Do not use this medicine after the expiry date.

Zydol SR description

What it looks like

50mg tablets- pale yellow round tablets imprinted with GRUNENTHAL logo on one side and engraved with "T0" on the other side.

100mg tablets- white round tablets imprinted with GRUNENTHAL logo on one side and engraved with "T1" on the other side.

150mg tablets- pale orange tablets imprinted with GRUNENTHAL logo on one side and engraved with "T2" on the other side.

200mg tablets- slightly brownish-orange coloured tablets imprinted with GRUNENTHAL logo on one side and engraved with "T3" on the other side.

All strengths are available in packs 20 or 60 tablets

Ingredients

This Active ingredient:

ZYDOL SR 50- 50 mg tramadol hydrochloride.

ZYDOL SR 100- 100 mg tramadol hydrochloride

ZYDOL SR 150- 150 mg tramadol hydrochloride

ZYDOL SR 200- 200 mg tramadol hydrochloride

Inactive ingredients:

- hypromellose
- colloidal anhydrous silica
- microcrystalline cellulose
- magnesium stearate

- lactose monohydrate
- macrogol 6000
- propylene glycol
- purified talc
- titanium dioxide
- quinoline yellow aluminium lake (150 and 200 mg tablets)
- iron oxide red (150 and 200 mg tablets)
- iron oxide yellow (50 and 200 mg tablets)
- iron oxide black (200 mg tablets).

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

AUST R: 121849 Tablets 50mg

AUST R: 80724 Tablets 100mg

AUST R: 80726 Tablets 150mg

AUST R: 80725 Tablets 200mg

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