

Consumer Medicine Information

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 is used for

Zydol SR is used to relieve moderate to severe pain and belongs to a group of medicines called analgesics (pain relievers).

Ask your doctor why Zydol has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

It is not normally addictive although some cases have been reported.

Before you use it

When you must not use it

Do not use Zydol SR if:

- you have a known allergy to Zydol SR or 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, e.g. morphine or codeine.
- you are taking medicine to treat depression containing a "monoamine oxidase inhibitor" (MAOI), such as Nardil or Parnate, or have taken one within the past two weeks.
- you have taken large amounts of alcohol or other substances which can affect your level of consciousness.
- you are having treatment for withdrawal from narcotics.
- any capsules look damaged or discoloured.

Do not use it after the expiry date printed on the pack.

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

Do not use Zydol SR if the packaging is torn or shows signs of tampering.

Do not give this medicine to children.

There is no experience with the use of Zydol SR in children.

If you are not sure whether you should be using Zydol SR, talk to your doctor.

Before you use it

You must tell your doctor if:

1. you have a known allergy to Zydol SR or any of the ingredients listed at the end of this leaflet.
2. you are known to be sensitive to opioids.
3. you drink alcohol every day.
4. you have or ever had any other health problems, including:
 - any lung or breathing problems
 - any diseases of the kidney, liver or pancreas
 - severe stomach problems
 - a serious head injury
 - any fits or convulsions/ epilepsy.
5. you have or have had any problems with drug or alcohol dependence.
6. you are pregnant or intend to become pregnant. Zydol SR is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using Zydol during pregnancy.
7. 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 it when breast-feeding.

If you have not told your doctor about any of the above, tell them before you use Zydol SR.

Taking other medicines

Tell your doctor 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)
- medicine for irregular or rapid heart beat
- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI'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.

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

How it is used

Zydol SR is available as tablets to swallow.

Your doctor will decide:

- what dose of the medicine you will receive and
- for how long.

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).

Patients over 75 years of age may require a lower daily dose.

The maximum daily dose should not exceed 400mg.

Follow carefully all directions given to you by your doctor and pharmacist.

These directions may differ from the information in this leaflet.

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

How to take it

Zydol SR tablets should be swallowed whole, with water.

They must NOT be chewed, crushed or dissolved as this will release all their contents with the potential of side effects occurring.

When to take it

You can take it before, with, or after food.

How long to take it

Depending on the medical condition for which you require Zydol SR, your doctor may tell you to take it for only a day or two or longer, up to a few months or more.

If you forget to take it

If you forget to take a dose, you can take it as soon as you remember. The next dose should be taken after four or six hours, or as prescribed by your doctor.

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

If you take too much (overdose)

Immediately telephone your doctor or the **Poisons Information Centre (tel: 13 11 26)** or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Zydol SR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many capsules, this may result in breathing difficulty and fits or convulsion.

While you are using Zydol SR

Things you must do

If you become pregnant while you are taking Zydol SR, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Zydol SR.

If your pain is not severe and you feel that you do not need as much Zydol SR as your doctor ordered, consult your doctor.

Tell your doctor if your pain gets worse. Do not take extra doses without checking with your doctor.

If you have to have any tests tell your doctor you are taking it. The medicine may affect the results of some tests.

Things you must not do

Do not give Zydol SR to anyone else, even if they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Zydol SR may make you drowsy or dizzy.

Ask your doctor for advice about whether it is safe for you to drive or operate machinery while taking Zydol SR.

Side effects

Check with your doctor as soon as possible if you have any problems while taking Zydol SR, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Zydol SR can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

Tell your doctor if you notice any of the following and they worry you.

Common side effects:

- dizziness, drowsiness, confusion
- headache
- nausea or vomiting
- tremor
- sweating

Less common side effects:

- changes in mood
- weakness
- constipation or stomach upsets
- dry mouth
- changes in appetite
- skin reactions
- difficulty in passing urine
- very low blood pressure
- Serotonin Syndrome: signs of this vary but may include fever, sweating, confusion, agitation, diarrhoea, muscle twitching, difficulty with walking and balance. This results from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.

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.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Can Zydol SR be addictive?

When used as prescribed by your doctor, addiction to Zydol SR is unlikely.

If you are taking the medicine for a prolonged period of time, your body may become used to it and mild withdrawal symptoms may occur if you suddenly stop taking the medicine.

It is important therefore to take it only as directed by your doctor.

Do not suddenly stop taking it.

Your dosage may need to be gradually reduced.

After using Zydol SR

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.

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.

Zydol 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- deep orange to brown 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

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
- silica-colloidal anhydrous
- microcrystalline cellulose
- magnesium stearate
- lactose monohydrate
- macrogol 6000
- propylene glycol
- talc
- titanium dioxide
- quinoline yellow aluminium lake CI47005 (150 and 200 mg tablets)
- iron oxide red CI77491 (150 and 200 mg tablets)
- iron oxide yellow CI 77492 (50 and 200 mg tablets)

- iron oxide black CI77499 (200 mg tablets).

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Date of Preparation:
July 2016

AUST R: 121849 Tablets 50mg

AUST R: 80724 Tablets 100mg

AUST R: 80726 Tablets 150mg

AUST R: 80725 Tablets 200mg

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