

DUROTRAM® XR

(duro-tram)

Tramadol hydrochloride (tram-ma-dol hy-dro-klor-ide)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Durotram XR. 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 this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Durotram XR is used for

Durotram XR is used to relieve moderate to severe pain. It belongs to the group of medicines called analgesics (pain relievers).

Durotram XR has been specially designed to release the pain reliever gradually over a 24-hour period, so that you need to only take one dose per day.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

When used as prescribed by your doctor, addiction to Durotram XR is very unlikely.

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

It is important, therefore, to take Durotram XR only as directed by your doctor.

Durotram XR is available only with a doctor's prescription.

Durotram XR is not recommended for the elderly (over 75 years) or children under the age of 18 years.

Before you take Durotram XR

When you must not take it

Do not take Durotram XR:

- **if you have ever had an allergic reaction to tramadol (the active ingredient) or any of the ingredients listed at the end of this leaflet;**

If you have an allergic reaction you may get a skin rash, have difficulty in breathing, get symptoms of hayfever or feel faint;

- **if you have an allergy to any other medicines known as opioid analgesics (e.g. morphine or codeine);**
- if you have taken large amounts of alcohol or other substances which can affect your level of consciousness;
- if you are taking medicine for depression containing a monoamine oxidase inhibitor

also known as MAOI, or have taken any oxidase inhibitor within the past two weeks. Examples of MAOI-containing medicines are phenelzine (Nardil) and tranylcypromine (Parnate);

- if you are undergoing treatment for withdrawal from narcotics
- if you are taking an antibacterial agent called linezolid (Zyvox);
- if you have seizures (convulsions) or have a condition that may put you at increased risk of seizures (epilepsy, head injury, metabolic disorders, alcohol or drug withdrawal);
- if you are breast-feeding and need to take Durotram XR for more than 2 to 3 days;
- if you have severe liver and kidney problems;

Durotram XR should not be used for minor pain that can be relieved by readily available (over the counter) painkillers.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Tell your doctor

- if you have lung or breathing problems;
- if you are known to be sensitive to opioids;
- if you have any disorder of the kidney, liver or pancreas, including any related to alcohol intake, for example, cirrhosis of the liver;
- if you have stomach problem;
- if you have a severe headache or have had a head injury;
- if you have, or have had, any drug or alcohol dependence;
- if you have had any fits or convulsions, or take medicine for epilepsy;
- if you are taking medicines for depression, or mental or psychiatric disorder or to help you sleep;
- if you are taking medication known as SSRIs, tricyclic antidepressants, quinidine, phenothiazines or anti psychotics;
- if you are taking the medicine carbamazepine (one brand name is Tegretol).

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Durotram XR.

Taking other medicines

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

Some medicines and Durotram XR may interfere with each other.

These include:

- carbamazepine ;

- coumarin derivatives (e.g. 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 (SSRIs), tricyclic antidepressants, quinidine, phenothiazines or anti-psychotics;
- some antibiotics.

These medicines may be affected by Durotram XR, or may affect how well it works.

You may need different amounts of your medicines, or you may need to take different medicines. Other interactions not listed above may also occur.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Durotram XR

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

These instructions may differ from the information contained in this leaflet.

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

How much to take

Durotram XR should be taken once daily, at approximately the same time every day.

How to take it

Durotram XR tablets should be swallowed whole with a glass of water.

It does not matter if you take this medicine before or after food.

The tablet must be swallowed whole and NOT be broken, chewed, crushed or dissolved because this might release the active ingredient more quickly and cause unpleasant side-effects.

When to take it

Durotram XR should be taken once daily, at approximately the same time every day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Do not stop taking Durotram XR unless your doctor tells you to.

Tell your doctor if your pain is not helped or gets worse.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, Poisons Information Centre (telephone number: 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or

anyone else may have accidentally taken too much Durotram XR.

Overdosage with Durotram XR will result in decrease in breathing and fits or convulsions.

While you are taking Durotram XR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Durotram XR

Tell any other doctors, dentists, or pharmacists who treats 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 become pregnant while taking this medicine, tell your doctor immediately.

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

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

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

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

This medicine may cause dizziness or drowsiness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Durotram XR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible 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 Durotram XR include:

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

The less common side effects of Durotram XR include:

- indigestion;
- changes in appetite;
- skin reactions;
- sudden onset of low blood pressure, collapse;
- muscle weakness;
- tremor;
- seizures;
- respiratory depression;
- improvement of mood;
- confusion;
- sleep disturbances;
- blurred vision;
- difficulty in passing urine;
- Serotonin Syndrome: signs of this vary and are not specific; they may include fever, sweating, confusion; agitation; diarrhoea; muscle twitching, difficulty with walking and balance. Serotonin syndrome may result from interaction of tramadol with other medicines which increase serotonin effects,

for example, SSRI antidepressants.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital, as urgent medical treatment may be needed:

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. You should remember that all medicines carry some risks. It is possible that some risks might not be detected despite many years of experience with the medicine.

After using Durotram XR

Storage

Keep your medicine in the original container until it is time to take it.

If you take the tablets out of the pack, they may not keep well.

Keep your tablets away from direct sunlight in a cool dry place where the temperature stays below 30°C.

Do not store Durotram XR or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep the medicine in a safe place where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any tablets you have left over.

Product description

What it looks like

Durotram XR is available as 100 mg, 200 mg and 300 mg tablets. They are white to off-white, plain, bevelled edge, round biconvex tablets.

All strengths of Durotram XR tablets are available in cartons containing 10 tablets. Physicians' sample packs containing 3 tablets are available for Durotram XR 100 mg and 200 mg.

Ingredients

Durotram XR tablets contain 100 mg, 200 mg or 300 mg of tramadol hydrochloride as the active ingredient.

They also contain:

- polyvinyl acetate;
- hydroxypropyl distarch phosphate;
- povidone;
- sodium lauryl sulfate;
- xanthan gum;
- vegetable oil hydrogenated;
- silica colloidal anhydrous;
- magnesium stearate.

Durotram XR does not contain gluten, tartrazine or any other azo dyes.

Sponsor

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200 mg tablet AUST R 134822

300 mg tablet AUST R 134823

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