

PART III: CONSUMER INFORMATION**TRIDURAL[®]****Tramadol hydrochloride extended-release tablets**

This leaflet is part III of a three-part “Product Monograph” published when TRIDURAL[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRIDURAL[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

TRIDURAL[®] (tramadol hydrochloride) is an oral tablet that slowly releases tramadol (an opioid analgesic) over a 24 hour period to manage pain that is expected to persist for several days or more. Your doctor is the person who knows if TRIDURAL[®] tablets are a good choice for you.

What it does:

TRIDURAL[®] is a medicine used to treat moderate to moderately severe pain and should relieve your pain and help the pain relief last longer.

Your pain may increase or decrease from time to time and your doctor may need to change the amount of tramadol you take daily (daily dosage).

When it should not be used:

TRIDURAL[®] should not be used if:

- Your doctor did not prescribe it for you;
- You are allergic to tramadol, opioids or to any of the non-medicinal ingredients in the product (see **What the non-medicinal ingredients are**). Contact your doctor immediately if you experience an allergic reaction (e.g., skin rash, hives) or any severe or unusual side effects;
- You are consuming large amounts of alcohol or taking excessive amounts of other drugs that can depress respiration/breathing and consciousness;
- You are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor medication (e.g., Nardil[®], Parnate[®]);
- You have severe kidney or liver disease.

TRIDURAL[®] should not be used for minor pain that can be relieved by readily available (over-the-counter) pain killers.

Children under 18 years of age should not take TRIDURAL[®] tablets.

Use of TRIDURAL[®] tablets in pregnant women is not recommended. It is not clear what effects the medication would have on the fetus.

TRIDURAL[®] tablets are not recommended for obstetrical preoperative medication or for post-delivery analgesia in nursing mothers because its safety in infants and newborns has not been studied.

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), are taking monoamine oxidase inhibitors, have an infection of the central nervous system, or are taking antidepressant medication, do not take this medication before discussing your history with your doctor.

Like some pain relievers, TRIDURAL[®] tablets may be habit forming. TRIDURAL[®] tablets may not be the best medicine for you if you have had problems with addiction, drug dependence, or drug abuse in the past. Tell your doctor and pharmacist if you have had these conditions before.

What the medicinal ingredient is:

TRIDURAL[®] tablets contain tramadol hydrochloride.

What the non-medicinal ingredients are:

Non-medicinal ingredients for TRIDURAL[®] are: ammonium hydroxide, colloidal silicon dioxide, Contramid[®] (modified starch), hydrogenated vegetable oil, iron oxide black, isopropyl alcohol, magnesium stearate, n-butyl alcohol, polyvinyl acetate, povidone, propylene glycol, shellac glaze, sodium lauryl sulfate, and xanthan gum.

What dosage forms it comes in:

TRIDURAL[®] extended-release tablets are available in three strengths, each containing 100 mg, 200 mg or 300 mg of tramadol hydrochloride, the active ingredient.

WARNINGS AND PRECAUTIONS

BEFORE you use TRIDURAL[®] be sure to tell your doctor if you have, or had in the past any other medical conditions (any liver, kidney, or abdominal problems, or if you had a previous head injury), are pregnant or plan to become pregnant, are breastfeeding, and if you are taking any other medications. This will help your doctor to decide

whether you should use TRIDURAL[®] and what extra care should be taken during its use.

Serious and rarely fatal allergic reactions (e.g., swelling of lips and throat, blistering of skin and/or lips or neck) have been reported in patients receiving therapy with tramadol. Seek medical attention immediately.

Seizures have been reported at therapeutic doses of tramadol and this risk may be increased at doses exceeding the usual upper daily dose limit.

If you are planning surgery, or about to undergo surgery, tell your doctor that you are taking TRIDURAL[®].

You should take the following precautions while taking TRIDURAL[®] tablets:

Alcohol

You must not consume alcohol while taking TRIDURAL[®] tablets as it may increase the chance of experiencing dangerous side effects. Also, you should tell your doctor if you drink alcohol regularly, or have a history of alcoholism.

Driving or operating machinery

Do not drive a car or operate other potentially hazardous machinery until you are sure that taking TRIDURAL[®] does not make you drowsy.

Other medications

You should not take other medications that contain tramadol while you are taking TRIDURAL[®] tablets.

There are also other drugs, such as tranquilizers, antidepressants, hypnotics, sleeping pills, or other analgesics, that cause some serious reactions when taken by someone who is also taking TRIDURAL[®] tablets. You must tell your doctor and pharmacist if you are taking any other over-the-counter or prescription medications – they will tell you what you should do.

INTERACTIONS WITH THIS MEDICATION

There are other medications that may cause TRIDURAL[®] tablets to be less effective, or may cause you to have some side effects or drug reactions.

Drugs that may interact with TRIDURAL[®] include:

- Alcohol or other sedative drugs may enhance the drowsiness caused by tramadol;
- Carbamazepine may increase the metabolism of tramadol and reduce the analgesic effect;
- Tricyclic antidepressants, selective serotonin re-uptake inhibitors (SSRIs), antipsychotics used concomitantly can lower the seizure threshold;
- Protease inhibitors (e.g., ritonavir) - co-administration may increase the blood levels of tramadol;
- Digoxin, warfarin or warfarin-like drugs - rare reports of toxicity have been reported when co-administered with tramadol.

You must tell your doctor and pharmacist if you are taking any other medications.

PROPER USE OF THIS MEDICATION

Usual adult dose:

TRIDURAL[®] should be swallowed whole with a sufficient quantity of liquid and not split, chewed, dissolved or crushed since this can lead to the rapid release and absorption of an excessive dose of tramadol, which can seriously harm you.

TRIDURAL[®] should be taken once daily at breakfast, at approximately the same time every day. Do not repeat your dose within 24 hours.

If your pain worsens, making you uncomfortable, contact your doctor - she/he may decide that it is necessary to adjust your daily dosage. **You should not take more than the maximum recommended dose of 300 mg of TRIDURAL[®] per day.** Exceeding this recommendation can result in respiratory depression (shallow, slow breathing), seizures, coma, heart stoppage and death.

Your dose of TRIDURAL[®] will be clearly labelled on the medication bottle. Be sure to follow the directions on the label exactly; this is very important. Do not increase or decrease your dose without consulting your doctor. If your dosage is changed by your doctor, be sure to write it down at the time your doctor calls or sees you, and follow the new directions exactly. Review your pain regularly with your doctor to determine if you still need TRIDURAL[®].

In patients with kidney problems, the time between doses may be longer. Please speak with your doctor.

Discontinuation:

Consult your doctor for instructions on how to stop this medicine slowly to avoid uncomfortable symptoms such as anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection and rarely hallucinations.

You should not stop taking TRIDURAL[®] all at once if you have been taking it for more than a few days.

Overdose:

The most important sign of overdose is decreased breathing (abnormally slow or weak breathing), or extreme drowsiness. If you accidentally take an overdose of TRIDURAL[®], contact your doctor and/or the nearest hospital or Emergency Room, and/or Poison Control Centre immediately, even though you may not feel sick.

Missed Dose:

It is very important that you do not miss any doses. If you miss one or more doses, take the next dose at the normal time and in the normal amount. Do not take two doses at once, unless your doctor tells you to. If you miss several doses in succession, talk to your doctor before restarting your medication.

Do not seek additional prescriptions for this medicine from any other doctor - unless responsibility for your pain management has been transferred to another doctor.

Should your pain increase, or any other complaint develop as a result of taking TRIDURAL[®] contact your doctor immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most medications have some side effects; however, not all people have the same side effects. When taking TRIDURAL[®] tablets the most common side effects include nausea, vomiting, constipation, headache, dizziness and sleepiness. Slower titration may be an effective way to reduce adverse effects. Your doctor may order a laxative and stool softener to help relieve your constipation while you are taking TRIDURAL[®]. Tell your doctor about these problems if they arise. If you experience serious symptoms or any other unusual symptoms, tell your doctor

immediately.

If you experience any symptoms related to an allergic reaction (such as a severe rash or hives), rapid heartbeat, chest pain, dizziness, leg swelling, low blood pressure, change in your mental status, difficulty in breathing, chest tightness, wheezing, fainting, or other serious or unusual symptoms, please consult a doctor or pharmacist immediately.

Physical dependence, abuse and withdrawal reactions have been rarely reported. See withdrawal reactions listed within the “**Discontinuation**” section of this leaflet.

This is not a complete list of side effects. For any unexpected effects while taking TRIDURAL[®] contact your doctor or pharmacist.

HOW TO STORE IT

TRIDURAL[®] tablets should be stored at room temperature (15°C to 30°C).

Keep TRIDURAL[®] in a secure place to prevent theft and misuse.

Do not give any of it to anyone other than the person for whom it was prescribed, since it may seriously harm them.

Do not use TRIDURAL[®] tablets after the expiry date. All expired medications should be returned to your pharmacist.

Keep this and all medicines in a safe place, and out of the reach of children. Accidental overdose with TRIDURAL[®] by a child is dangerous and may result in death.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
 toll-free fax: 866-678-6789
 By email: cadrmp@hc-sc.gc.ca

By regular mail:
 National AR Centre
 Marketed Health Products Safety and Effectiveness
 Information Division
 Marketed Health Products Directorate
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.labopharm.com>
 or by contacting the sponsor, Labopharm Inc., at:
 1-800-686-1017

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