PART III: CONSUMER INFORMATION

Pr® DURELA®
Tramadol Hydrochloride
Extended-Release Capsules

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

Keep DURELA® in a safe place away from children and pets. Accidental use by a child is a medical emergency and may result in death. If a child accidentally comes in contact with DURELA® get emergency help right away.

Please read this before you start using DURELA®. Remember this information does not take the place of your doctor’s instructions.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT DURELA®?

- Do not break, chew, dissolve or crush DURELA® capsules. If DURELA® is taken this way, tramadol will be released too fast. This can lead to serious and life-threatening breathing problems. Life-threatening breathing problems can also happen because of an overdose or if the dose you are using is too high for you. Get emergency medical help immediately if you:
  - Have trouble breathing, or have slow or shallow breathing
  - Have a slow heartbeat
  - Have severe sleepiness
  - Have cold, clammy skin
  - Feel faint, dizzy, confused or cannot think, walk, or talk normally
  - Have a seizure
  - Have hallucinations

- DURELA® is not for use to treat pain that you only have once in a while (“as needed”).
- Never give DURELA® to anyone else, even if they have the same symptoms as you have. It may harm them or even cause death.
- Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep DURELA® in a safe place to protect it from being stolen.
- After you stop taking DURELA® you should take the unused capsules to your pharmacist to be destroyed.

What the medication is used for:
DURELA® is an oral capsule that slowly releases tramadol (an opioid analgesic) over a 24 hour period to manage moderate or moderately severe pain that is expected to persist for several days or more.

What it does:
Tramadol is a medicine used to treat moderate or moderately severe pain and should 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:
DURELA® should not be used if:
- Your doctor did not prescribe it for you;
- You are allergic to tramadol, opioids or any other ingredient in the capsules (see What the nonmedicinal ingredients are);
- You are consuming alcohol or taking other drugs that can depress respiration/breathing and consciousness;
- You are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor medications (e.g., phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline);
- You have severe kidney or liver disease.

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

Individuals under 18 years of age should not take DURELA® capsules.

Use of DURELA® capsules in pregnant women is not recommended. It is not clear what effects the medication would have on the fetus.

Use of DURELA® capsules in nursing women is not recommended.

If you have had seizures (convulsions) or have a condition that may put you at increased risk of seizures (epilepsy, head injury, metabolic disorders, central nervous system (CNS) infection, alcohol or drug withdrawal) do not take this medication before discussing your history with your doctor.

Like some other pain relievers, DURELA® may be habit forming. Tell your doctor and pharmacist if you have a history of substance abuse or addiction.

What the medicinal ingredient is:
Tramadol Hydrochloride USP

What the nonmedicinal ingredients are:
Corn starch, D & C Red #7 calcium lake (E180), D & C Yellow #10 aluminum lake, Eudragit NE 30D, FD & C Blue #2 aluminum lake (E132), gelatin, hypromellose, lactose monohydrate 200 mesh, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone K30, propylene glycol,

DURELA® (tramadol hydrochloride extended-release capsules) Product Monograph
shellac, simethicone emulsion, sodium starch glycolate, sucrose stearate, talc and titanium dioxide.

**What dosage forms it comes in:**
Extended-release capsules: 100 mg, 200 mg, and 300 mg.
DURELA® capsules are white, marked as follows:

- 100 mg: “G 252” on cap and “100” between lines on the body in blue ink
- 200 mg: “G 253” on cap and “200” between lines on the body in violet ink
- 300 mg: “G 254” on cap and “300” between lines on the body in red ink

**WARNINGS AND PRECAUTIONS**

BEFORE you use DURELA®, talk to your doctor or pharmacist if you have, or had in the past any other medical conditions (diabetes, any liver, kidney or abdominal problems), are over 65 years of age, are pregnant or plan to become pregnant, are breast feeding, have had problems with addiction, drug dependence or drug abuse, and if you are taking any other medications.

DURELA® can decrease your blood sugar levels. Diabetic patients may need to monitor their blood sugar more often. If you notice changes, discuss this with your doctor.

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 DURELA®. You should take the following precautions while taking DURELA® capsules:

- You must not consume alcohol while taking DURELA®, as it may increase the chance of experiencing dangerous side effects; you should tell your doctor if you drink alcohol regularly, or have a history of alcoholism;
- Driving or other tasks requiring full alertness should not be attempted until you are sure that taking DURELA® does not make you drowsy;
- 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**

Drugs that may interact with DURELA® 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.

**PROPER USE OF THIS MEDICATION**

DURELA® capsules should be swallowed whole and should not be broken, 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.

DURELA® is not recommended for rectal administration.

**Usual adult dose:**
Take the dose prescribed by your doctor. DURELA® capsules should be taken regularly every 24 hours (with 4 to 6 oz. of water) to prevent pain all day and night. The usual starting dose of DURELA® is 100 mg per day.

DURELA® capsules may be taken with or without food.

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

Your dose of DURELA® 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 DURELA®.

**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 DURELA® all at once if you have been taking it for more than a few days.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Make sure you take your medicine with you to show the doctor.
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 DURELA®, contact your doctor immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

DURELA® can cause abnormal blood test results including decreased blood sugar. Your doctor will decide when to perform blood tests and will interpret the results.

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<th>Symptom/ effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and seek immediate medical help</th>
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<td>Decreased Blood Sugar (hypoglycemia): dizziness, lack of energy, drowsiness, headache, trembling, sweating</td>
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The most common side effects you may experience are constipation, dizziness, drowsiness, headache, nausea, and vomiting. Your doctor may order a laxative and stool softener to help relieve your constipation while you are taking DURELA®. Tell your doctor about these problems if they arise.

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 DURELA®, contact your doctor or pharmacist.

HOW TO STORE IT
Store at room temperature (15-30°C).
Keep DURELA® 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.
Keep DURELA® out of sight and reach of children. Accidental overdose by a child is dangerous and may result in death.

REPORTING SUSPECTED SIDE EFFECTS
You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by using one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION
This leaflet summarized important information about DURELA®. If you would like more information, talk with your doctor and/or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.medfutures.com
or by contacting Medical Futures Inc., at:
1-866-789-2090

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