

PART III: CONSUMER INFORMATION

PrDETROL LA®

(tolterodine L-tartrate extended release capsules)

This leaflet is part III of a three-part "Product Monograph" published when DETROL LA (tolterodine L-tartrate extended release capsules) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DETROL LA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

The name of this medication is DETROL LA. It is used for the treatment of the symptoms of overactive bladder which include frequency, urgency, and urge incontinence.

REMEMBER: This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

What it does:

Tolterodine works to prevent bladder contractions or spasms. This results in more bladder capacity and less frequency, urgency and involuntary loss of urine.

When it should not be used:

You should **not** take DETROL LA if you have:

- urinary retention,
- gastric retention,
- uncontrolled narrow angle glaucoma,
- known hypersensitivity to tolterodine L-tartrate or any of the other ingredients in DETROL LA.

What the medicinal ingredient is:

Each capsule contains film-coated beads of 2 mg or 4 mg of the active ingredient, tolterodine L-tartrate. The film-coated beads dissolve over time, releasing the active ingredient over 24 hours.

What the important nonmedicinal ingredients are:

The capsules also contain the following inactive ingredients: Sucrose, starch, hypromellose, ethylcellulose, ammonium hydroxide, medium chain triglycerides, oleic acid, gelatin and FD & C Blue 2. The 2 mg capsules also contain yellow iron oxide. Both capsule strengths are imprinted with a pharmaceutical grade ink, Opacode White S-1-7085 that contains shellac glaze, titanium dioxide, ammonium hydroxide, propylene glycol and simethicone.

What dosage forms it comes in:

DETROL LA 2 mg capsules have a blue-green symbol and "2" printed in white ink.

DETROL LA 4 mg capsules have a blue symbol and "4" printed in white ink.

WARNINGS AND PRECAUTIONS

DETROL LA may have an effect on the electrical activity of the heart. This effect can be measured as a change in the electrocardiogram (ECG). It is important to follow the instructions of your doctor with regard to dosing or any special tests. In very rare cases, drugs with an effect on the ECG can lead to disturbances in heart rhythm (arrhythmias/dysrhythmias). These heart rhythm disturbances are more likely in patients with risk factors, such as heart disease, or in the presence of certain interacting drugs. If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid pounding, or irregular heart beat), fainting, or seizures, you should stop taking DETROL LA and seek immediate medical attention.

BEFORE you use DETROL LA talk to your doctor or pharmacist if:

- you are pregnant, or trying to become pregnant
- you are breastfeeding your child
- you have myasthenia gravis (a chronic autoimmune neuromuscular disease which cause muscle weakness)
- you have stomach problems affecting passage and digestion of food
- you have liver problems
- you have kidney problems
- you are taking medication bought without a prescription. They may affect your condition, or how DETROL LA works for you.
- you are a female or are over 65 years in age; you have a disorder known as Long QT Syndrome; a heart disease; a history of stroke or brain hemorrhage; a personal history of fainting spells; a family history of sudden cardiac death at <50 years; electrolyte disturbances (e.g., low blood potassium levels); an eating disorder or are following an extreme diet; diabetes, especially with associated nerve disorders

INTERACTIONS WITH THIS MEDICATION

The following list includes some, but not all, of the drugs that may increase the risk of side effects while receiving DETROL LA. You should check with your doctor or pharmacist before taking any other medication with DETROL LA.

Drugs that may interact with DETROL LA include:

- other drugs that possess antimuscarinic/anticholinergic properties (drugs that cause blurred vision, constipation, dry mouth, etc.)
- antifungals (drugs to treat fungal infections, such as, fluconazole, ketoconazole, or itraconazole)
- antibiotics (ie. erythromycin, clarithromycin)
- cyclosporine (a drug to prevent rejection of organ transplants)
- vinblastine (a drug to treat some types of cancer)
- antiarrhythmics (drugs that stabilize the heart rhythm function, such as procainamide, quinidine, amiodarone,

- sotalol, etc.)
- antidepressants (mood disorder drugs)
- antipsychotics (drugs to stabilize thinking and behavior)
- anti-asthmatic (salmeterol)

PROPER USE OF THIS MEDICATION

Take DETROL LA as instructed by your doctor. Do not increase, decrease or stop taking DETROL LA without first talking to your doctor.

Usual dose:

The usual starting dose is 4 mg once daily, but may be decreased to 2 mg once daily. The capsule should be swallowed whole. DETROL LA can be taken with food.

Overdose:

Do not take more capsules than your doctor has told you to. If you take too many capsules by accident, call your doctor or pharmacist or a poison control centre immediately.

Missed Dose:

If you miss taking your capsule, take it as soon as you remember. But if it is almost time for the next dose, skip the missed dose and just take the next dose. Do not take more than one dose at a time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, DETROL LA can cause some side effects.

Tell your doctor or pharmacist right away if you suffer from any of the following side effects while taking this medication:

- dry mouth
- stomach pain
- decreased tear production (dry irritable eye)
- heartburn
- blurred vision
- dizziness
- palpitations (sensation of rapid, pounding, or irregular heart beat)
- fainting
- difficulty in urination (passing water)

The most common side effect is dry mouth. Less commonly reported side effects are headache, constipation, dizziness, fatigue, abdominal pain and dry eyes.

If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should stop taking DETROL LA and seek immediate medical attention.

Check with your doctor or pharmacist right away if you have **any** bothersome or unusual effects while taking DETROL LA.

Use caution while driving or using machinery until you know how DETROL LA affects you.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Allergic reaction			√

This is not a complete list of side effects. For any unexpected effects while taking DETROL LA, stop taking the drug and contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature 15°C to 30°C. Protect from light.

You should not use your medication after the expiration date printed on the carton and label.

Keep all medications out of the reach of children. This medication could harm them.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by 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, or
 - 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 on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

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

MORE INFORMATION

This document plus the full Product Monograph, prepared for Health Professionals can be found at:

<http://www.viatris.ca>
<http://www.detrol.ca>

or by contacting the sponsor, BGP Pharma ULC, at 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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