

PART III: CONSUMER INFORMATION

Pr**DETROL**[®] tolterodine L-tartrate tablets

This leaflet is part III of a three-part "Product Monograph" published when DETROL 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. 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. 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 prevents 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 if you have:

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

What the medicinal ingredient is:

Each tablet contains 1 mg or 2 mg of the active ingredient tolterodine L-tartrate.

What the important nonmedicinal ingredients are:

The tablets also contain the following inactive ingredients: colloidal anhydrous silica, calcium hydrogen phosphate dihydrate, hypromellose, magnesium stearate, cellulose microcrystalline, sodium starch glycolate, stearic acid, and titanium dioxide.

What dosage forms it comes in:

DETROL 1 mg tablets are white and marked with curved lines above and below the lettering "TO".

DETROL 2 mg tablets are white and marked with curved lines above and below the lettering "DT".

WARNINGS AND PRECAUTIONS

DETROL 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 and seek immediate medical attention.

BEFORE you use DETROL 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 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. You should check with your doctor or pharmacist before taking any other medication with DETROL.

Drugs that may interact with DETROL 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 as instructed by your doctor. Do not increase, decrease or stop taking DETROL without first talking to your doctor.

Usual dose:

The usual starting dose is 2 mg twice daily, but may be decreased to 1 mg twice daily.

Overdose:

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

Missed Dose:

If you should forget to take your tablet at the usual time, take it as soon as you remember unless it is time to take the next one. Continue with the remaining doses as before. Do not take more than one dose at a time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, DETROL 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
- 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 effects are dry mouth and headache. Less commonly reported side effects are dizziness, fatigue, abdominal pain, constipation and heartburn.

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 and seek immediate medical attention.

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

Use caution while driving or using machinery until you know how DETROL 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, stop taking the drug and contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature 15°C to 30°C.

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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