

Management of Overdosage

Overdosage with DETROL LA Capsules can potentially result in severe central anticholinergic effects and should be treated accordingly.

ECG monitoring is recommended in the event of overdosage. In dogs, changes in the QT interval (slight prolongation of 10% to 20%) were observed at a suprapharmacologic dose of 4.5 mg/kg, which is about 68 times higher than the recommended human dose. In clinical trials of normal volunteers and patients, QT interval prolongation was observed with tolterodine immediate release at doses up to 8 mg (4 mg bid) and higher doses were not evaluated (see **PRECAUTIONS, Patients with Congenital or Acquired QT Prolongation**).

DOSAGE AND ADMINISTRATION

The recommended dose of DETROL LA Capsules are 4 mg daily. DETROL LA should be taken once daily with liquids and swallowed whole. The dose may be lowered to 2 mg daily based on individual response and tolerability, however, limited efficacy data is available for DETROL LA 2 mg (see **CLINICAL STUDIES**).

For patients with significantly reduced hepatic or renal function or who are currently taking drugs that are potent inhibitors of CYP3A4, the recommended dose of DETROL LA is 2 mg daily (see **CLINICAL PHARMACOLOGY** and **PRECAUTIONS, Drug Interactions**).

HOW SUPPLIED

DETROL LA Capsules 2 mg are blue-green with symbol and 2 printed in white ink. DETROL LA Capsules 4 mg are blue with symbol and 4 printed in white ink. DETROL LA Capsules are supplied as follows:

Bottles of 30		Bottles of 500	
2 mg Capsules	NDC 0009-5190-01	2 mg Capsules	NDC 0009-5190-03
4 mg Capsules	NDC 0009-5191-01	4 mg Capsules	NDC 0009-5191-03
Bottles of 90		Unit Dose Blisters	
2 mg Capsules	NDC 0009-5190-02	2 mg Capsules	NDC 0009-5190-04
4 mg Capsules	NDC 0009-5191-02	4 mg Capsules	NDC 0009-5191-04

Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature]. Protect from light.

Rx only



LAB-0256-6.0

March 2008

PATIENT INFORMATION

DETROL[®] LA (DE-trol el-ay)

(tolterodine tartrate extended release capsules)

Read the Patient Information that comes with DETROL LA before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or your treatment. Only your doctor can determine if treatment with DETROL LA is right for you.

What is DETROL LA?

DETROL LA is a prescription medicine for **adults** used to treat the following symptoms due to a condition called **overactive bladder**:

- having a strong need to urinate with leaking or wetting accidents (urge urinary incontinence)
- having a strong need to urinate right away (urgency)
- having to urinate often (frequency)

DETROL LA did not help the symptoms of overactive bladder when studied in children.

What is overactive bladder?

Overactive bladder happens when you cannot control your bladder muscle. When the muscle contracts too often or cannot be controlled, you get symptoms of overactive bladder, which are leakage of urine (urge urinary incontinence), needing to urinate right away (urgency), and needing to urinate often (frequency).

Who should not take DETROL LA?

Do not take DETROL LA if:

- you have trouble emptying your bladder (also called "urinary retention")

- your stomach empties slowly (also called "gastric retention")
- you have an eye problem called "uncontrolled narrow-angle glaucoma"
- you are allergic to DETROL LA or to any of its ingredients. See the end of this leaflet for a complete list of ingredients

What should I tell my doctor before starting DETROL LA?

Before starting DETROL LA, tell your doctor about all of your medical conditions, including if you:

- have any stomach or intestinal problems
- have trouble emptying your bladder or you have a weak urine stream
- have an eye problem called narrow-angle glaucoma
- have liver problems
- have kidney problems
- have a condition called myasthenia gravis
- or any family members have a rare heart condition called QT prolongation (long QT syndrome)
- are pregnant or trying to become pregnant. It is not known if DETROL LA could harm your unborn baby
- are breastfeeding. It is not known if DETROL LA passes into your milk and if it can harm your child

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Other drugs can affect how your body handles DETROL LA. Your doctor may use a lower dose of DETROL LA if you are taking:

- Certain medicines for fungus or yeast infections such as Nizoral[®] (ketoconazole), Sporanox[®] (itraconazole), and Monistat[®] (miconazole)
- Certain medicines for bacteria infections such as Biaxin[®] (clarithromycin), and erythromycin
- Sandimmune[®] (cyclosporine) or Velban[®] (vinblastine)

Know the medicines you take. Keep a list of them with you to show your doctor or pharmacist each time you get a new medicine.

How should I take DETROL LA?

- Take DETROL LA exactly as prescribed. Your doctor will prescribe the dose that is right for you. Do not change your dose unless told to do so by your doctor.
- Take DETROL LA capsules once a day with liquid. Swallow the whole capsule. Tell your doctor if you cannot swallow a capsule.
- DETROL LA can be taken with or without food.
- Take DETROL LA the same time each day.
- If you miss a dose of DETROL LA, begin taking DETROL LA again the next day. Do not take 2 doses of DETROL LA in the same day.
- If you took more than your prescribed dose of DETROL LA, call your doctor, or poison control center, or go to the hospital emergency room.

What are possible side effects of DETROL LA?

The most common side effects with DETROL LA are:

- dry mouth
- headache
- constipation
- stomach pain

Medicines like DETROL LA can cause blurred vision, dizziness, or drowsiness.

Use caution while driving or doing other dangerous activities until you know how DETROL LA affects you.

These are not all the side effects with DETROL LA. For a complete list, ask your doctor or pharmacist.

How do I store DETROL LA?

- Store DETROL LA at room temperature (59 to 86° F) out of the light. Keep it in a dry place.

- **Keep DETROL LA and all medicines out of the reach of children.**

General Information about DETROL LA

Medicines are sometimes prescribed for conditions that are not in the patient information leaflet. Only use DETROL LA the way your doctor tells you. Do not share it with other people even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about DETROL LA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DETROL LA that is written for health professionals. You can also visit www.DETROLA.com on the Internet, or call 1-888-4-DETROL (1-888-433-8765).

What are the ingredients in DETROL LA?

Active ingredients: tolterodine tartrate

Inactive ingredients: sucrose, starch, hypromellose, ethylcellulose, medium chain triglycerides, oleic acid, gelatin, and FD&C Blue #2. 2mg capsule also contains yellow iron oxide. Capsules have pharmaceutical grade printing ink that contains shellac glaze, titanium dioxide, propylene glycol, and simethicone.

Distributed by:



LAB-0312-3.0

March 2008

Registered trademarks are the property of their respective owners.

Revised: 03/2008

Distributed by: Pfizer Inc