







## DRUG CLASS AND MECHANISM

Tolterodine belongs to a class of drugs called cholinergic (acetyl-choline) receptor blockers. It is used to treat disorders of the urinary bladder that affect urination.

The urinary bladder is a muscular "bag." Urine coming from the kidneys fills the bladder and causes it to stretch like a balloon. As it stretches, pressure in the bladder increases and, when the bladder reaches a certain level of stretch, a desire to urinate is felt. Nerves in the muscular wall of the bladder release acetyl- choline, a chemical that attaches to receptors on the muscle cells and causes the cells to contract (tighten). This contributes further to the increase in pressure within the bladder and the desire to urinate. At the appropriate time (e.g., when a toilet is available), there is conscious relaxation of the muscle at the outlet of the bladder, and the high bladder pressure forces urine out of the bladder. Normally, urination is under conscious control; however, in some individuals normal control as well as normal sensation are lost. The desire to urinate may be felt when there is little urine in the bladder, and urination may occur without warning or control. By blocking the effect of acetyl-choline on the muscle cells, tolterodine slows the build-up of pressure in the bladder, reduces the sensation to urinate, and prevents uncontrolled urination. The FDA approved tolterodine in 1998. An extended release form of tolterodine, (Detrol LA) was approved by the FDA in 2001.

## GENERIC AVAILABLE: no

## **PRESCRIPTION:** yes

**PREPARATIONS:** Tolterodine tablets: 1mg and 2mg. Long acting tolterodine capsules: 2mg and 4 mg.

#### PRESCRIBED FOR

Tolterodine is used to treat uncontrollable urination due to what is often referred to as an "overactive" bladder. Symptoms include the need to urinate frequently, an urge to urinate immediately, and an inability to control urine release (urinary incontinence).

## DOSING

Tolterodine usually is taken twice daily. The starting dose is 2mg twice daily. With the long-acting tolterodine, the starting dose is 4mg daily, and may be reduced to 2mg if the larger dose is not tolerated. The dose may need to be reduced for patients who have impaired function of the liver or kidneys. Caution is recommended for patients with narrow-angle glaucoma, obstruction to the flow of urine, or poor emptying of the stomach since these medical conditions may worsen with tolterodine administration.

#### **DRUG INTERACTIONS**

Tolterodine follows a specific path through the liver in order to be eliminated from the body. Drugs that block this path may slow the elimination of tolterodine, raise tolterodine blood levels, and lead to side effects. No formal studies have been conducted showing such interactions, however. The list of drugs that might possibly interfere with the elimination of tolterodine includes is erythromycin, clarithromycin (Biaxin), ketoconazole (Nizoral), itraconazole (Sporanox), and miconazole (Monistat, Micatin). The dose of tolterodine should be reduced to 1mg twice daily if taken with any of these drugs.

#### USES

This medication is used to treat an overactive bladder.

#### HOW TO USE

Take this product by mouth exactly as directed by you doctor. Your dosage depends on your condition and response to therapy. This medication may be taken with or without food. The sustained release form must be swallowed whole. Do not crush or chew them.

## SIDE EFFECTS

Dry mouth, dry eyes, headache, constipation, nausea, dizziness or drowsiness may occur. If these effects persist or worsen, notify your doctor promptly. To relieve dry mouth, suck on (sugarless) hard candy or ice chips, chew (sugarless) gum, drink water or use saliva substitute. Report promptly:

symptoms of urinary infection (e.g., urinary burning, urgent and frequent urination). Unlikely but report promptly: vision problems, eye pain, difficulty with urination, severe stomach pain, chest pain, fast heartbeat, hot/dry skin, mental or mood changes. If you notice other effects not listed above, contact your doctor or pharmacist.

## PRECAUTIONS

Tell your doctor your medical history, including: any allergies, difficulty with urination (urinary retention or prostate enlargement in males), stomach/intestinal disorders (e.g., gastric retention), glaucoma (narrow angle), liver problems, kidney problems. Limit alcohol intake, as it may aggravate certain side effects of this drug. Caution is advised when performing tasks requiring mental alertness (e.g., driving). This medication may reduce sweating which can lead to heat stroke in hot weather. Consult your doctor or pharmacist. Caution is advised in the elderly, who may be more sensitive to side effects should they occur. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug is excreted into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

## DRUG INTERACTIONS

Tell your doctor of all nonprescription and prescription medication you may use, especially of: macrolide antibiotics (e.g., erythromycin, clarithromycin), azole antifungals (e.g., ketoconazole, itraconazole), anti-Parkinson's drugs (e.g., benztropine, trihexyphenidyl, other antimuscarinic drugs (e.g., scopolamine, dicyclomine), oxybutynin, cyclosporine, vinblastine. Also report other drugs which may cause drowsiness, such as: anti-anxiety or anti-seizure drugs, sedatives, tranquilizers, narcotic pain relievers, psychiatric medicines (e.g., chlorpromazine or amitriptyline), muscle relaxants, antihistamines that cause drowsiness (e.g., diphenhydramine). Check the labels on all your medicines (e.g., caugh-and-cold . products) because they may contain drowsiness-causing ingredients. Ask your pharmacist about the safe use of those products. Do not start or stop any medicine without doctor or pharmacist approval.

## OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include difficulty urinating, difficult breathing, dilated pupils, fast heartbeat, excitation, hallucinations, and seizures.

#### **MISSED DOSE**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

#### STORAGE

Store at room temperature between 66 and 77 degrees F (20-25 degrees C) away from light and moisture.

**Note**: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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