

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986**

This medicine is dispensed with a doctor's prescription only

**Detrusitol® SR 2 mg**

Each slow release capsule contains:  
Tolterodine L-tartrate 2 mg

**Detrusitol® SR 4 mg**

Each slow release capsule contains:  
Tolterodine L-tartrate 4 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 "Further information".

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**1. WHAT IS THIS MEDICINE INTENDED FOR?**

A preparation with anti-muscarinic activity intended for the treatment of overactive bladder with symptoms of urinary frequency, urgency and/or urge incontinence.

**Therapeutic group:** Muscarinic receptor antagonist.

**2. BEFORE USING THIS MEDICINE**

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You have difficulties emptying the urinary bladder (also called "urinary retention").
- Your stomach is emptying slowly (also called "gastric retention").
- You have an eye problem called "uncontrolled narrow angle glaucoma".
- You are sensitive to medicines containing the substance fesoterodine.

**Special warnings regarding use of the medicine**

**Before treatment with Detrusitol® SR, tell your doctor if:**

- You have a gastric problem or digestive problems.
- You have a difficulty emptying the urinary bladder or weak urine flow.
- You have an eye problem called "narrow angle glaucoma".
- You have liver problems.
- You have a kidney problem.
- You have a condition called myasthenia gravis.
- You or any of your family members have a rare heart problem called "QT interval prolongation" (prolonged QT syndrome).
- You are pregnant or breastfeeding, planning to become pregnant or to breastfeed – see section "Pregnancy and breastfeeding".

**Children and adolescents**

There is no information regarding the effectiveness of using this preparation in children and adolescents.

**Drug interactions**

**If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

Other medicines may affect the manner of handling Detrusitol® SR by your body. The doctor may prescribe a lower dose if you are taking:

- Certain medicines for fungal or yeast infections such as ketoconazole, itraconazole, miconazole.
- Certain medicines for bacterial infections such as clarithromycin.
- Certain medicines for treatment of HIV infection such as ritonavir, saquinavir, atazanavir.

You should know the medicines you take. Keep the list of medicines with you to show the doctor or pharmacist each time you get a new medicine.

**Using this medicine and food**

You can take the capsule with or without food.

**Pregnancy, breastfeeding and fertility**

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor before taking this medicine. It is not known whether Detrusitol® SR may harm the fetus.

If you are breastfeeding or planning to breastfeed, consult your doctor or pharmacist before taking this medicine. It is not known whether Detrusitol® SR passes into breast milk and whether it may harm the baby.

**Driving and using machines**

Do not drive, operate dangerous machines or perform other dangerous activities until you know how Detrusitol® SR affects you. Anti-muscarinic medicines, such as Detrusitol® SR, may cause side effects such as blurred vision, dizziness or somnolence.

**Important information about some of this medicine's ingredients**

The capsule contains sucrose – if you have been told by the doctor that you have intolerance to certain sugars, contact the doctor before taking the medicine.

**3. HOW TO USE THIS MEDICINE?**

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

**The dosage and treatment regimen will be determined by your doctor only. Do not change the dosage unless you have been instructed to do so by the doctor.**

**The standard dosage is usually:**

One capsule once a day with a glass of water. Swallow the capsule at whole since this is a mechanism of slow release. Tell the doctor if you cannot swallow capsules.

Take the capsule at the same time every day.

**Do not exceed the recommended dose.**

**If you have taken an overdose, or if a child has accidentally swallowed some medicine,** immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine** at the scheduled time, take the next dose on the following day. Do not take 2 doses of the medicine at the same day.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

**Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Detrusitol® SR, may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**Stop taking Detrusitol® SR and seek medical help immediately if you experience the following symptoms:**

Detrusitol® SR may cause allergic reactions that may be serious. Symptoms of a serious allergic reaction may include swelling of the face, lips, throat, or tongue, difficulty breathing, respiratory tract obstruction or a drop in blood pressure.

##### **Common side effects:**

The most common side effects of Detrusitol® SR are:

- Dry mouth
- Headache
- Constipation
- Abdominal pain

##### **Additional side effects**

Dizziness, indigestion, tiredness, dry eye, blurred vision, sleepiness, anxiety, sinusitis, pain upon urination.

Severe allergic reaction (anaphylaxis) and subcutaneous edema, rapid heartbeats (tachycardia), strong heartbeats (palpitations), peripheral edema (edema in the legs), diarrhea, confusion, disorientation, memory impairment, hallucinations.

Reports of exacerbation of dementia symptoms (e.g., confusion, disorientation, delusions) have been obtained after Detrusitol® SR treatment was initiated in patients taking cholinesterase inhibitors for the treatment of dementia.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

#### **5. HOW TO STORE THE MEDICINE?**

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.

#### **6. FURTHER INFORMATION**

**In addition to the active ingredient, this medicine also contains:**

##### **Detrusitol® SR 2 mg:**

Sugar spheres, ethylcellulose, medium chain triglycerides, oleic acid, ammonium hydroxide, purified water, hydroxypropyl methylcellulose, gelatin, yellow iron oxide, titanium dioxide and FD&C Blue #2.

Each 2 mg capsule contains 67.23 mg sugar.

##### **Detrusitol® SR 4 mg:**

Detrusitol SR PIL CC 17052020

Sugar spheres, ethylcellulose, medium chain triglycerides, oleic acid, ammonium hydroxide, purified water, hydroxypropyl methylcellulose, gelatin, titanium dioxide and FD&C Blue #2. Each 4 mg capsule contains 134.5 mg sugar.

**What the medicine looks like and contents of the pack:**

Detrusitol® SR 2 mg - a blue-green capsule with white printed text.

Detrusitol® SR 4 mg - a blue capsule with white printed text.

Each pack contains 28 capsules.

**Registration holder and address:** Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725, Israel.

**Manufacturer's name and address:** Pfizer Italia, S.R.L., Italy

**Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:**

Detrusitol® SR 2 mg: 125-56-30466

Detrusitol® SR 4 mg: 125-55-30467

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