PATIENT INFORMATION LEAFLET

Read this leaflet carefully before you start using this medicine.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **This medicine has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.**

SCHEDULING STATUS: S3

PROPRIETARY NAME (AND DOSAGE FORM):

DETRUSITOL® SR 2 mg Prolonged release capsules

DETRUSITOL® SR 4 mg Prolonged release capsules

WHAT DETRUSITOL SR CONTAINS:

The active substance is tolterodine L-tartrate 2 mg and 4 mg.

The other (inactive) ingredients are sucrose, maize starch, ethylcellulose, medium chain triglycerides, oleic acid, hypromellose, gelatine (bovine), shellac glaze, titanium dioxide (E171), simethicone and propylene glycol. The blue- green prolonged release capsules also contain colourants: yellow iron oxide (E 172) and FD&C Blue #2.

WHAT DETRUSITOL SR IS USED FOR:

DETRUSITOL SR belongs to a class of antimuscarinic medicines, which relaxes the muscle of the bladder. This medication is used for the treatment of urge incontinence and symptoms such as needing to rush to the toilet with no advance warning, needing to go to the toilet frequently and/or not getting to the toilet in time and wetting yourself. These symptoms may occur if you have an unstable/overactive bladder.

BEFORE TAKING DETRUSITOL SR:

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Do not use DETRUSITOL SR:

- If you have ever had an allergic reaction to any of the ingredients in DETRUSITOL SR.
- If you suffer from reduced ability to empty the bladder.
- If you suffer from reduced ability to empty the stomach (gastric retention).
- If you suffer from high pressure and pain in the eyes.
- If you suffer from a disorder of neuromuscular function – the muscles and nerves affecting your entire body.
- If you have acute dilation/swelling of the colon associated with amoebic or ulcerative colitis.

Take special care before treatment with DETRUSITOL SR:

- If you have an acutely distended, painful abdomen, affecting the passage and digestion of food.
- If you have difficulty passing urine and/or poor stream of urine.
- If you are on treatment for glaucoma (high pressure and pain in the eyes).
- If you have liver problems. In this case the doctor will lower the usual dose.
- If you have kidney problems. In this case the doctor may choose to lower the usual dose.
- If you suffer from a muscle disorder causing weakness.
- If you suffer from a nerve problem which sometimes occurs with diabetes and can lead to diarrhoea, impotence or low blood pressure (autonomic neuropathy).
- If you have hiatus hernia (a part of the stomach which protrudes into the chest cavity).

Pregnancy and Breastfeeding:

DETRUSITOL SR should not be taken if you are pregnant or breastfeeding as it may affect the baby. Women of childbearing potential should only take DETRUSITOL SR if they are using adequate contraception.

Driving and using machinery:

DETRUSITOL SR can sometimes cause dizziness, fatigue and blurred vision. This may impair your ability to concentrate and react. If you are affected, do not drive or operate machinery during treatment with DETRUSITOL SR.

Taking other medicines with DETRUSITOL SR:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Before you start taking DETRUSITOL SR, make sure your doctor knows if you are:

- Taking macrolide antibiotics (e.g. erythromycin and clarithromycin).
- Being treated for fungal infections (ketoconazole, itraconazole and miconazole).
- Using medicines containing fluoxetine – a type of medicine to treat depression.
- Taking Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic medications – (medicines to treat an irregular heartbeat).

HOW TO TAKE DETRUSITOL SR:

Do not share medicines prescribed for you with others.

Always take DETRUSITOL SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you accidentally taken too many capsules, tell your doctor or pharmacist as soon as possible. Do not take a double dose to make up for forgotten individual doses.

The prolonged release capsules can be taken with or without food and must be swallowed whole.

The usual dose in adults is one 4 mg prolonged release capsule once daily. The recommended dose for patients with impaired kidney function or impaired liver function is one 2 mg prolonged release capsule once daily. For patients receiving ketoconazole or other related medication, the recommended dose is 2 mg once daily.

Your doctor will tell you how long your treatment with DETRUSITOL SR will last. Do not stop treatment early because you do not see an immediate effect. If you have any concerns, please discuss these with your doctor.

POSSIBLE SIDE EFFECTS:

DETRUSITOL SR can have side effects. Not all side effects reported for DETRUSITOL SR are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

DETRUSITOL SR may cause mild to moderate effects like dry mouth, heartburn, indigestion or eye discomfort and dry eyes. Other common side effects which may affect less than 1 out of 10 but more

than 1 out of 100 patients are listed below.

Bronchitis, sinusitis, dizziness, headache, somnolence, abnormal vision, dry eyes (decreased tear production), vertigo (dizziness), stomach pain or discomfort, constipation, indigestion, flatulence, dry skin, difficulty or pain in passing urine, chest pain, fatigue and increased weight.

During post marketing surveillance, patients have also experienced disorientation, hallucinations and memory impairment.

QTc prolongation has also occurred in patients receiving medications to treat irregular heartbeat.

Should any of these symptoms occur or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist immediately.

STORAGE AND DISPOSAL INFORMATION:

Store all medicines out of reach of children.

Do not store above 25 °C.

Store the plastic bottle in the original container and keep the blister strip in the outer carton to protect from light.

Do not take DETRUSITOL SR after the expiry date shown on the blister or bottle label and carton. If your capsules are out of date, take them to your pharmacist who will get rid of them safely.

PRESENTATION:

DETRUSITOL SR capsules are available in white HDPE bottles each containing 30, 90 or 500 capsules or clear, colourless PVC/PVDC film and aluminium foil blister strips containing either 7 or 14 capsules. Each strip is packed into an outer carton which may contain either 7, 28, 49, 84 or 280 capsules.

IDENTIFICATION OF DETRUSITOL SR:

DETRUSITOL SR 2 mg: Blue-green capsules with white printing (figurine and 2) containing multi-layer white film-coated beads.

DETRUSITOL SR 4 mg: Blue capsules with white printing (figurine and 4) containing multi-layer white film-coated beads.

REGISTRATION NUMBERS:

DETRUSITOL SR 2 mg: 36/5.4/0448

DETRUSITOL SR 4 mg: 36/5.4/0449

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE:

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando

Gauteng, 1609

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Manufacturer: Catalent Pharma Solutions, LLC, Kentucky, USA

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09 September 2009

BOTSWANA: S2

DETRUSITOL SR 2 mg – Reg. No.: BOT0801410

DETRUSITOL SR 4 mg – Reg. No.: BOT0801411

NAMIBIA: NS2

DETRUSITOL SR 2 mg – Reg. No.: 04/5.4/2084

DETRUSITOL SR 4 mg – Reg. No.: 04/5.4/2085