PACKAGE LEAFLET: INFORMATION FOR THE USER

Deterodine SR 4 mg prolonged-release capsules

tolterodine tartrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Deterodine SR is and what it is used for
2. What you need to know before you take Deterodine SR
3. How to take Deterodine SR
4. Possible side effects
5. How to store Deterodine SR
6. Contents of the pack and other information

1. W hat Deterodine SR is and what it is used for

The active substance in Deterodine SR is tolterodine tartrate. Tolterodine belongs to a class of medicinal products called antimuscarinics.

Deterodine SR is used in adults and the elderly for the treatment of the symptoms of overactive bladder syndrome. If you have overactive bladder syndrome, you may find that you are unable to control urination or you need to rush to the toilet with no advance warning and/or go to the toilet frequently.

2. What you need to know before you take Deterodine SR

Do not take Deterodine SR
- if you are allergic to tolterodine or any of the other ingredients of this medicine (listed in section 6)
- if you are unable to pass urine from the bladder (urinary retention)
- if you have high pressure in the eyes with loss of eyesight that is not being adequately treated (uncontrolled narrow-angle glaucoma)
- if you suffer from excessive weakness of the muscles (myasthenia gravis)
- if you suffer from severe ulceration and inflammation of the colon (severe ulcerative colitis)
- if you suffer from acute widening of the colon (toxic megacolon).

Warnings and precautions

Talk to your doctor or pharmacist before taking Deterodine SR if you:
- have difficulties in passing urine and/or a poor stream of urine
- have a gastro-intestinal disease that affects the passage and/or digestion of food
- suffer from kidney problems (renal insufficiency)
- have a liver condition
- suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- have a hiatal hernia (a hernia in the upper part of stomach)
- ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility)

- have a heart condition such as:
    - an abnormal heart tracing (ECG)
    - a slow heart rate (bradycardia)
    - have a pre-existing heart disease such as cardiomyopathy (weak heart muscle), myocardial ischaemia (reduced blood flow to the heart), arrhythmia (irregular heartbeat) and heart failure
- have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Talk to your doctor or pharmacist before starting your treatment with Deterodine SR if you think any of these might apply to you.

Other medicines and Deterodine SR
Tolterodine tartate, the active substance of Deterodine SR, may interact with other medicinal products.

It is not recommended to take this medicine in combination with:
- some antibiotics (e.g. erythromycin, clarithromycin)
- medicinal products used for the treatment of fungal infections (e.g. ketoconazole, itraconazole)
- medicinal products used for the treatment of HIV.

Deterodine SR should be used with caution when taken in combination with:
- medicines that affect the passage of food (e.g. metoclopramide and cisapride);
- medicines for the treatment of irregular heartbeat (e.g. amiodarone, sotalol, quinidine, procainamide);
- other medicines with a similar mode of action to Deterodine SR (antimuscarinic properties) or medicines with an opposite mode of action to Deterodine SR (cholinergic properties). Ask your doctor if you are unsure.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Taking Deterodine SR with food and drink
Deterodine SR can be taken before, after or during a meal.

Pregnancy and breast-feeding
Pregnancy
You should not take Deterodine SR when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to have a baby.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Deterodine SR is not recommended for mothers who are breast-feeding.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Do not drive or operate machinery whilst taking Deterodine SR as it may make you feel dizzy, tired or affect your sight.

Deterodine SR contains sucrose (a type of sugar)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Deterodine SR

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 4 mg prolonged-release capsule daily. For patients who have a kidney or a liver condition or troublesome side effects, your doctor may reduce your dose to one 2 mg prolonged-release capsule daily.

Use in Children
Deterodine SR is not recommended for children.

The prolonged-release capsules should be swallowed whole with a glass of water with or without food. Do not chew the capsules.

Duration of treatment
Your doctor will tell you how long your treatment with Deterodine SR will last. Your bladder will need some time to adapt. Do not stop treatment early because you do not see an immediate effect. Finish the course of prolonged-release capsules prescribed by your doctor. If you have not noticed any effect by then, talk to your doctor.

The benefit of the treatment should be re-evaluated after 2 or 3 months.

If you take more Deterodine SR than you should
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately or go to the nearest hospital emergency department.

Signs of overdose to look for are: hallucinations, severe excitation, convulsions, increased heart beat, shortness of breath, difficulty to pass urine or widening of pupils.

If you forget to take Deterodine SR
If you forget to take a dose at the usual time, take it as soon as you remember unless it is almost time for your next dose. In that case, omit the forgotten dose and follow the normal dose schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Deterodine SR
Do not stop taking this medicine unless your doctor advises you to stop.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should see your doctor immediately or go to the hospital emergency department if you experience symptoms of angioedema such as:
- swollen face, tongue, throat
- difficulty to swallow
- hives and difficulty in breathing

You should also seek medical attention if you experience a hypersensitivity reaction (for example itching, rash, hives or difficulty breathing). This occurs uncommonly (occurs in less than 1 in 100 patients).

Tell your doctor immediately or go to the hospital emergency department if you notice any of the following:
- chest pain, difficulty breathing or getting tired easily (even at rest), difficulty breathing at night, swelling of the legs.

These may be symptoms of heart failure. This occurs uncommonly (occurs in less than 1 in 100 patients).

The following side effects have been observed during treatment with Deterodine SR with the following frequencies.

Very common side effects (may affect more than 1 in 10 patients)
- dry mouth

Common side effects (may affect up to 1 in 10 patients)
- sinusitis
- dizziness, sleepiness, headache
- dry eyes, blurred vision
- difficulty with digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine
- painful or difficult urination
- tiredness
- extra fluid in the body causing swelling (e.g. in the ankles)
- diarrhoea

Uncommon side effects (may affect up to 1 in 100 patients)
- allergic reactions
- nervousness
- sensation of pins and needles in the fingers and toes
- feeling of spinning, dizziness (vertigo)
- palpitations, heart failure, irregular heartbeat
- inability to empty the bladder
- chest pain
- memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, angioedema, dry skin, and disorientation. There have also been reports of worsening symptoms of dementia in patients being treated for dementia.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Deterodine SR

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Deterodine SR contains
The active substance is tolterodine tartrate. Each prolonged-release capsule contains 4 mg of tolterodine tartrate which is equivalent to 2.74 mg of tolterodine.

The other ingredients are sugar spheres (sucrose and maize starch), ethylcellulose (E462), hypromellose (E464) and talc (E553b). The capsule shell contains indigo carmine (E132), titanium dioxide (E171) and gelatin (E441). The printing ink contains shellac (E904), propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide.

What Deterodine SR looks like and contents of the pack
Deterodine SR 4 mg prolonged-release capsules are powder-blue opaque, hard-shell gelatin capsules filled with white to off-white beads. The capsules are marked with MYLAN over 3404 in black ink on both parts of the capsule.

Your medicine is packed in perforated unit dose or in standard blisters containing 28x1 or 7, 10, 14, 20, 28, 30, 49, 60, 84, 90, 98 and 100 prolonged-release capsules and in bottles containing 30, 100, 250 and 500 prolonged-release capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer
Generics [UK] Limited, Station Close, Potters Bar, Herts, EN6 1TL, United Kingdom

Mylan Hungary Kft., H-2900, Komárom,Mylan utca 1, Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Tolterodin Arcana 4 mg Retardkapseln
Czech Republic	Tolterodin Mylan 4 mg, tvrdé tobolky s prodlouženým uvolňováním
Denmark	Tolterodin Mylan
Finland	Tolterodin Mylan
Greece	Tolterodine/Generics 4mg prolonged-release capsules
Germany	Tolterodin Mylan 4 mg Hartkapseln, retardiert
Ireland	Deterodine SR 4mg prolonged release capsules
Norway	Tolterodin Mylan
Romania	Tolterodină Generics 4mg capsule cu eliberare prelungită
Spain	Tolterodina Neo MYLAN 4 mg cápsulas duras de liberación prolongada EFG
Sweden	Tolterodin Mylan
The Netherlands	Tolterodinetartraat Retard 4 mg, capsules met verlengde afgifte, hard
United Kingdom	Efflosomyl XL 4mg prolonged-release capsules

This leaflet was last revised in April 2013.