PIL Title : Detrusitol
PIL Date : 08 December 2015
Country : Malaysia
References : 2 mg Detrusitol Film-coated tablet of Malaysia LPD. Information for the user dated 9 April 2007
Reason : New document

DETRUSITOL FILM-COATED TABLETS

Tolterodine L - tartrate (2 mg)

What is in this leaflet

What Detrusitol is used for

Detrusitol is used 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;
- you need to rush to the toilet with no advance warning and/or go to the toilet frequently.

How Detrusitol works

Detrusitol belongs to a class of medicines called antimuscarinics. It works by reducing spasm and relaxing the bladder muscles.

Before you use Detrusitol

-When you must not use it

Do not take Detrusitol if you:
- are allergic (hypersensitive) to tolterodine or any of the other ingredients in Detrusitol;
- are unable to pass urine (urinary retention);
- have an uncontrolled narrow-angle glaucoma (uncontrolled high pressure in the eyes);
- suffer from myasthenia gravis (excessive weakness of the muscles);
- suffer from severe ulcerative colitis (ulceration and inflammation of the colon);
- suffer from a toxic megacolon (acute expansion of the colon).

Pregnancy and lactation

The safety of Detrusitol during pregnancy has not yet been proven. You should use Detrusitol only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

It is not known if Detrusitol is excreted in the mother's breast milk. Breast-feeding is not recommended during the usage of Detrusitol.

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

-Before you start to use it

Check with your doctor before you use this medicine
- if you have difficulties in passing urine and/or a poor stream of urine;
- if you have a gastro-intestinal disease that blocks the passage of food;
- if you suffer from kidney problems (renal insufficiency);
- if you have a liver disease;
- if you suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system);
- if you have a hiatal hernia (protrusion of upper part of stomach;
- if you ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility);
- if you have a heart condition, such as an abnormal heart tracing (ECG) and slow heart rate (bradycardia);
- if you have abnormally low levels of potassium (hypokalaemia), magnesium (hypomagnesaemia) or calcium (hypocalcaemia) in your blood;
- if you have relevant pre-existing heart diseases, such as:
  - cardiomyopathy (weak heart muscle);
  - myocardial ischaemia (reduced blood flow to the heart);
  - arrhythmia (irregular heartbeat) and
  - heart failure.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

It is not recommended to use Detrusitol in combination with
- some antibiotics (e.g. erythromycin, clarithromycin);
- medicines used for the treatment of fungal infections (e.g. ketoconazole, itraconazole);
- antiproteases (medicines used for the treatment of HIV);
- 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 Detrusitol (antimuscarinic properties) or medicines with an opposite mode of action to Detrusitol (cholinergic properties).

How to use Detrusitol

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual dose is one 2 mg tablet twice daily, except for people who have a kidney or a liver condition or troublesome side effects in which case your doctor may reduce your dose to one 1 mg tablet twice daily.

Detrusitol is not recommended for children.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Detrusitol for as long as your doctor recommends.

-If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause accommodation disturbances such as blurred and double vision and difficulties in passing urine.

While you are using it
-Things you must do
Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Detrusitol.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do
Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Detrusitol to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of
Driving and using machines
This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects
Like all medicines, Detrusitol can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:
- inflammation of lining of airway;
- allergic reactions;
- confusion;
- dizziness, headache, sleepiness;
- blurred vision, dry eyes;
- vertigo (a feeling of dizziness or "spinning");
- flushed skin;
- dry mouth, abdominal pain, constipation, indigestion, excessive amounts of air or gases in the stomach or the intestine, heartburn;
- dry skin;
- painful or difficult urination, inability to empty the bladder;
- chest pain, tiredness;
- increased weight.

Side effects reported during post-marketing experience:
- serious allergic reaction which causes difficulty in breathing or dizziness;
- disorientation (alteration of mental status), hallucination (seeing, hearing or feeling things that are not really there);
- memory impairment;
- increased heart rate, feeling your heartbeat;
- diarrhoea;
- skin reaction which causes swelling of the face, lips, mouth, tongue or throat
- swelling of the ankles, feet or hands.

There have also been reports of worsening symptoms of dementia (confusion, alteration of mental status, delusion [false belief that is not grounded in reality and persists despite obvious evidence that it is mistaken]) in people being treated for dementia.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.mv (Consumers→Reporting).

Storage and Disposal of Detrusitol
- Storage
Keep out of the reach and sight of children.

Do not store above 25°C. Keep tablets in the original package, protected from moisture.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
-What it looks like
Film-coated tablets.

The film-coated tablets are white, round and biconvex. The 2 mg tablet is engraved with arcs above and below the letters DT.

-Ingredients
- Active ingredient
Tolterodine tartrate

- Inactive ingredients
Core:
Cellulose, microcrystalline
Calcium hydrogen phosphate dihydrate
Sodium starch glycollate (Type B)
Magnesium stearate, colloidal anhydrous silica

Film coating:
Coating granules containing Hypromellose, cellulose, microcrystalline, stearic acid
Titanium dioxide E171

-MAL number

MAL 19991686A
Manufacturer
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Marino Del Tronto
Ascoli Piceno, Italy

Product Registration Holder
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