

DETRUSITOL®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking DETRUSITOL?

DETRUSITOL contains the active ingredient tolterodine tartrate. DETRUSITOL is used to treat symptoms of an overactive bladder, for example urinary frequency, urgency or incontinence.

For more information, see Section [1. Why am I taking DETRUSITOL?](#) in the full CMI.

2. What should I know before I take DETRUSITOL?

Do not take if you have ever had an allergic reaction to DETRUSITOL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take DETRUSITOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DETRUSITOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take DETRUSITOL?

- The usual dose is 1 mg or 2 mg twice daily. Your doctor will prescribe the dose that is right for you.
- Take your medicine at about the same time each day.

More instructions can be found in Section [4. How do I take DETRUSITOL?](#) in the full CMI.

5. What should I know while taking DETRUSITOL?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking DETRUSITOL.
- Tell your doctor if symptoms of your overactive bladder do

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| | not improve, or if they become worse. |
| Things you should not do | <ul style="list-style-type: none"> • Do not stop taking your medicine or lower the dosage unless your doctor tells you to, even if you are feeling better. • Do not take DETRUSITOL to treat any other complaints unless your doctor tells you to. |
| Driving or using machines | <ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how DETRUSITOL affects you. DETRUSITOL may cause dizziness and blurred vision in some people. |
| Drinking alcohol | <ul style="list-style-type: none"> • Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness may be worse. |
| Looking after your medicine | <ul style="list-style-type: none"> • Keep your tablets in the blister until it is time to take them. |

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while taking DETRUSITOL?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you: dry mouth; heartburn; headache; constipation, stomach pain or diarrhoea; dry eyes; nausea; tiredness; swollen ankles.

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; dizziness or confusion; fits; fast heartbeat or palpitations; shortness of breath and swelling of the feet or legs; blurred vision; difficulty or pain in urinating (passing water); hallucinations (seeing, hearing or feeling things that are not really there).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DETRUSITOL®

Active ingredient(s): *tolterodine tartrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking DETRUSITOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking DETRUSITOL.**

Where to find information in this leaflet:

- [1. Why am I taking DETRUSITOL?](#)
- [2. What should I know before I take DETRUSITOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take DETRUSITOL?](#)
- [5. What should I know while taking DETRUSITOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking DETRUSITOL?

DETRUSITOL contains the active ingredient tolterodine tartrate. DETRUSITOL belongs to a group of medicines called antispasmodics. It helps to control the release of urine by reducing spasm, and relaxing the smooth muscle of the bladder wall. It also increases the

storage volume of the bladder, and can act on the brain to delay the desire to urinate.

DETRUSITOL is used to treat symptoms of an overactive bladder, for example urinary frequency, urgency or incontinence.

Ask your doctor if you have any questions about why DETRUSITOL has been prescribed for you.

This medicine is not addictive.

Do not give DETRUSITOL to children.

Safety and effectiveness of DETRUSITOL in children have not been established.

2. What should I know before I take DETRUSITOL?

Warnings

Do not take DETRUSITOL if:

- you are allergic to tolterodine, any of the ingredients listed at the end of this leaflet or any other similar medicines.

Always check the ingredients to make sure you can take this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- you are unable to pass urine
- you have a blocked gastro-intestinal tract or other gastro-intestinal disorders (ulcerative colitis, toxic megacolon)
- you have uncontrolled high pressure in the eye (narrow angle glaucoma)
- you have a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs (myasthenia gravis)

Do not take DETRUSITOL after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking DETRUSITOL, talk to your doctor.

Check with your doctor if you:

- you have allergies to any other medicines, foods, preservatives or dyes
- you have or have had any of the following medical conditions:
 - kidney or liver problems
 - heart problems
 - problems with urine retention
 - intestinal blockage or other intestinal or stomach problems

- autonomic neuropathy (a nerve problem which sometimes occurs with diabetes and can lead to diarrhoea, impotence or low blood pressure)
- hiatus hernia (a part of the stomach protrudes through the diaphragm, causing belching and heart burn)
- severe constipation
- raised pressure in the eye(s)
- take any medicines for any other condition.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take DETRUSITOL.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking DETRUSITOL during pregnancy.

Do not take DETRUSITOL if you are breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with DETRUSITOL and affect how it works. These include:

- some medicines used to treat depression, such as: fluoxetine, amitriptyline
- certain medicines used to treat irregular heart beats: flecainide, quinidine, procainamide, disopyramide, sotalol, amiodarone
- some antifungals: fluconazole, ketoconazole, itraconazole, miconazole
- some antibiotics: erythromycin, clarithromycin
- cisapride, a medicine used to treat heartburn/reflux and related intestinal disorders
- metoclopramide, a medicine used to treat nausea and gastric retention
- tranquillisers, such as: haloperidol, chlorpromazine, thioridazine, pimozide
- anti-proteases, medicines used to treat HIV infection, such as: ritonavir, indinavir
- droperidol, a medicine used to prevent or reduce nausea and vomiting.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking DETRUSITOL.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DETRUSITOL.

4. How do I take DETRUSITOL?

How much to take

- The usual dose is 1 mg or 2 mg twice daily.
- Your doctor will prescribe the dose that is right for you.
- Follow all directions given to you by your doctor or 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.

When to take DETRUSITOL

- Take your medicine at about the same time each day. Taking DETRUSITOL at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take DETRUSITOL before or after food.

How to take DETRUSITOL

- Swallow the tablets whole with a full glass of water.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Your doctor should re-assess your condition at regular intervals, for example after 6 months, to determine how long you need to keep taking DETRUSITOL for.

If you forget to take DETRUSITOL

DETRUSITOL should be taken regularly at the same time each day. **If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much DETRUSITOL

If you think that you or anyone else have taken too much DETRUSITOL, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26 and New Zealand telephone 0800 POISON or 0800 764 766) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

The symptoms of taking too much DETRUSITOL may include shortness of breath, fits, fast heart beat, inability to pass urine, dilated pupils, feeling excited or hallucinations.

5. What should I know while taking DETRUSITOL?

Things you should do

- If symptoms of your overactive bladder do not improve, or if they become worse, tell your doctor.

- If you are about to start taking any new medicine, remind your doctor and pharmacist that you are taking DETRUSITOL.
- If you become pregnant while taking DETRUSITOL, tell your doctor.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking DETRUSITOL. It may affect other medicines used during surgery.
- Always discuss with your doctor any problems or difficulties during or after taking DETRUSITOL.

Remind any doctor, dentist or pharmacist you visit that you are taking DETRUSITOL.

Things you should not do

- Do not take DETRUSITOL to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you or their symptoms seem similar to yours.
- Do not stop taking your medicine or lower the dosage unless your doctor tells you to, even if you are feeling better.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DETRUSITOL affects you.

DETRUSITOL may cause dizziness and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Looking after your medicine

- Keep your tablets in the blister until it is time to take them. If you take the tablets out of the blister they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DETRUSITOL.

This medicine helps most people with an overactive bladder, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following lists of possible side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• Dry mouth• Heartburn• Headache• Constipation, stomach pain or diarrhoea• Dry eyes• Nausea• Tiredness• Swollen ankles | Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none">• Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing• Dizziness or confusion• Fits• Fast heartbeat or palpitations | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

| Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● Shortness of breath and swelling of the feet or legs ● Blurred vision ● Difficulty or pain in urinating (passing water) ● Hallucinations (seeing, hearing or feeling things that are not really there) | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or New Zealand at <https://nzphvc.otago.ac.nz/reporting>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DETRUSITOL contains

| | |
|---|---|
| Active ingredient (main ingredient) | tolterodine tartrate 1 mg or 2 mg per tablet |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• microcrystalline cellulose• calcium hydrogen phosphate dihydrate• sodium starch glycollate• magnesium stearate• silica colloidal anhydrous• hypromellose• stearic acid• titanium dioxide |

Do not take this medicine if you are allergic to any of these ingredients.

What DETRUSITOL looks like

DETRUSITOL 1 mg tablet is a white, round, biconvex, film-coated tablet, engraved with arcs above and below the letters "TO" (AUST R 99393).

DETRUSITOL 2 mg tablet is a white, round, biconvex, film-coated tablet, engraved with arcs above and below the letters "DT" (AUST R 99394).

DETRUSITOL tablets are available in blister packs of 56 tablets.

Who distributes DETRUSITOL

Viatrix Pty Ltd

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30-34 Hickson Road

Millers Point NSW 2000

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Distributed in New Zealand by:

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