

Consumer Medicine Information

ARROW – TOLTERODINE 1 & ARROW TOLTERODINE 2

1 mg & 2 mg Tablets

Tolterodine L-Tartrate

What is in this leaflet

This leaflet answers some common questions about Arrow - Tolterodine 1 & Arrow - Tolterodine 2. It does not contain all the available information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Arrow - Tolterodine 1 & Arrow - Tolterodine 2 is used for

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 is used to treat symptoms of an overactive bladder, for example, urinary frequency, urgency or incontinence.

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 belong to a group of medicines called antimuscarinics. 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, **Ask your doctor if you have any questions about why Arrow - Tolterodine 1 & Arrow - Tolterodine 2 has been prescribed for you.**

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

Before you take Arrow - Tolterodine 1 & Arrow - Tolterodine 2

When you must not take it

Do not take Arrow - Tolterodine 1 & Arrow - Tolterodine 2 if:

1. you have an allergic reaction to:

- tolterodine or any other antimuscarinic medicine,
- any of the other ingredients listed at the end of this leaflet.

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.

2. you are unable to pass urine.

3. you have uncontrolled high pressure in the eye (narrow-angle glaucoma).

4. you are breast-feeding or plan to breast-feed.

Do not take Arrow - Tolterodine 1 or Arrow - Tolterodine 2 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.

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 should not be given to children. Safety and effectiveness of Arrow - Tolterodine 1 & Arrow - Tolterodine 2 in children have not been established.

Before you start to take it

Tell your doctor if:

1. you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

2. you have or have ever had:

kidney or liver problems,

heart problems,

problems with passing urine,

gastrointestinal (stomach or gut) problems, including severe constipation,

raised pressure in the eye(s).

3. you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2 during pregnancy.

Taking other medicines

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

Some medicines and Arrow - Tolterodine 1 & Arrow - Tolterodine 2 may interfere with each other. These include medicines to treat:

- irregular heart beats, such as quinidine, procainamide, amiodarone, sotalol,
- fungal infection, such as ketoconazole, itraconazole and miconazole,
- bacterial infection, such as erythromycin and clarithromycin.

These medicines may be affected by Arrow - Tolterodine 1 or Arrow - Tolterodine 2 or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2.

How to take Arrow - Tolterodine 1 or Arrow - Tolterodine 2

Your doctor or pharmacist will tell you how to take your medicine.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

The normal dose is 2mg twice daily, taken with or without food. The dose may need to be decreased to 1mg twice daily if you experience troublesome side effects. Your doctor will prescribe the dose that is right for you. Arrow - Tolterodine 1 & Arrow - Tolterodine 2 may take up to 4 weeks before you see

the maximum benefit of treatment.

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 Arrow - Tolterodine 1 or Arrow - Tolterodine 2 for.

If you forget to take it

If 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 it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of you getting an unwanted side effect.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre - the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 or go to Accident and Emergency (Casualty) at your nearest hospital, if you think that you or anyone else may have taken too much Arrow - Tolterodine 1 or Arrow - Tolterodine 2. Do this even if there are no signs of discomfort or poisoning.

The symptoms of taking too much Arrow - Tolterodine 1 or Arrow - Tolterodine 2 may include shortness of breath, fits, fast heartbeat, in ability to pass urine, dilated pupils, feeling excited, or hallucinations.

While you are taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2

Things you must do

- If symptoms of your unstable bladder do not improve, or if they become worse, tell your doctor.
- If you become pregnant while you are taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2, tell your doctor.
- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- Be careful driving or operating machinery until you know how Arrow - Tolterodine 1 or Arrow - Tolterodine 2 affects you. As Arrow - Tolterodine 1 or Arrow - Tolterodine 2 may cause dizziness and blurred vision, you will need to take extra care.
- If you are about to start taking any new medicines, remind your doctor and pharmacist that you are taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2.
- Always discuss with your doctor any problems or difficulties during or after taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2.

Things you must not do

- Do not stop taking your medicine until your doctor tells you to, even if you are feeling better.
- Do not give Arrow - Tolterodine 1 or Arrow - Tolterodine 2 to anyone else, even if they have the same condition as you.
- Do not use Arrow - Tolterodine 1 or Arrow - Tolterodine 2 to treat any other medical complaints unless your doctor tells you to.

Side effects

Tell your doctor as soon as possible if you have any problems while taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2 , even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like many medicines, Arrow - Tolterodine 1 & Arrow - Tolterodine 2 may cause side effects. If they occur, they are likely to be minor and temporary. However, some may be serious and require medical attention.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Dry mouth
- Heartburn
- Headache
- Constipation, flatulence or stomach pain
- Dry eyes
- Weight gain
- Tiredness

Tell your doctor immediately if you notice any of the following:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Dizziness or confusion
- Blurred vision
- Difficulty or pain in urinating (passing water)
- Skin rash
- Shortness of breath, chest pain or irregular heartbeats (fast heartbeat or palpitations Swollen ankles
- Seeing, hearing or feeling things that are not really there (hallucinations)

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2

Storage

- Keep your tablets in the blister until it is time to take them.
- Keep the tablets in a cool dry place where the temperature stays below 25°C.
- Do not store Arrow - Tolterodine 1 or Arrow - Tolterodine 2, or any other medicines, in a bathroom or near a sink.
- Do not leave Arrow - Tolterodine 1 or Arrow - Tolterodine 2 in the car or on windowsills. Heat and dampness can destroy some medicines.
- Keep Arrow - Tolterodine 1 & Arrow - Tolterodine 2 where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Arrow - Tolterodine 1 or Arrow - Tolterodine 2, or you find that it has passed the expiry date, ask your pharmacist what to do with the medicine you have left over.

Product Description

What Arrow - Tolterodine 1 & Arrow - Tolterodine 2 looks like

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 tablets are available in blister packs containing 14/28/56 tablets. There are 2 strengths of tablets available, 1mg and 2mg.

Arrow - Tolterodine 1 Tablets 1mg are presented as White to off white, round, biconvex, film coated tablet, debossed with "S16" on one side and plain on other side

Arrow - Tolterodine 2 Tablets 2mg are presented as White to off white, round, biconvex, film coated tablet, debossed with "S042" on one side and plain on other side.

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 are available in PVC/PVdC -Alu blister packs

Each pack contains 14/28/56 tablets.

Ingredients

Active ingredients

- Tolterodine Tartrate

Inactive Ingredients:

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 Tablets 1mg and 2mg also contain: microcrystalline cellulose(E460),Sodiumstarchglycolate(Type-A),colloidalsilicon dioxide(E551), magnesium stearate(E572),hydroxypropyl methylcellulose(E464),titanium dioxide(E171), macrogol, ,Talc (E553b)

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 does not contain sucrose, gluten, tartrazine or other azo dyes.

Further Information

Arrow - Tolterodine 1 & Arrow - Tolterodine 2 Tablets 1mg and 2mg is a Prescription Only Medicine.

Name & Address

Distributed in New Zealand by:
Arrow Pharmaceuticals (NZ) Ltd.
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