



AQUIETTE® 2.5 mg Tablets

Oxybutynin hydrochloride

Read all of this leaflet carefully before you start taking this medicine – because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- This product is for women with symptoms of overactive bladder who:
 - are between 18 and 65 years of age
 - have had symptoms for more than 1 month **and**
 - in whom bladder training alone for at least 6 weeks has not been enough to control symptoms.
- **You must stop taking Aquiette and talk to a pharmacist or doctor if your symptoms are not under control or get worse after taking Aquiette Tablets for 6 weeks.**
- **It is important that you do exercises to help train your bladder at the same time as taking these tablets. A ‘Bladder Training Plan’ and advice on your drinking habits can be found at the end of this leaflet.**

What is in this leaflet

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

1. What Aquiette is and what it is used for

What Aquiette is

Aquiette contains the active substance oxybutynin hydrochloride. Oxybutynin belongs to a group of medicines called ‘anti-cholinergics’ or ‘anti-spasmodics’.

How Aquiette works

Aquiette relaxes the muscle of the bladder wall so the bladder can expand more before telling you that it is full. This helps control the feeling that you have an urgent need to pass water (urine).

What Aquiette is used for

Aquiette is used for women with an overactive bladder who are between 18 and 65 of age, when symptoms have been present for more than 1 month **and** when bladder training alone for at least 6 weeks is not enough to control symptoms.

The following are signs of an overactive bladder:

- a sudden urgent need to pass water with little or no warning (called ‘urinary urgency’), usually with:
 - having to pass water more than 8 times in 24 hours (urinary frequency)
 - getting up in the night more than once to pass water (nocturia)

- sometimes with an occasional loss of control leading to accidental leaking or wetting when the urgent need to pass water cannot be resisted (urge incontinence).

Aquiette will not work if you only have accidental urine loss when you laugh, cough, sneeze or exercise. This may be something called ‘stress incontinence’.

2. What you need to know before you take Aquiette

Do not take Aquiette if:

- your symptoms have been present for less than 1 month
- you are a woman under 18 or over 65 years old
- you are pregnant, planning to become pregnant or breast-feeding (see ‘Pregnancy and breastfeeding’)
- you have diabetes, heart disease or kidney disease – you should not take these tablets unless told to by your doctor; these illnesses can make you pass water more often
- you have a known nerve condition which causes bladder problems
- you are allergic to oxybutynin or any of the ingredients of this medicine (listed in section 6); signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- you have or have had a known condition that causes a blockage in your urinary system that makes it difficult for you to pass water, e.g. kidney stones or bladder cancer
- you have or have had a rare muscle illness called ‘Myasthenia gravis’
- you have or have had glaucoma (increased pressure in the eye) that is not being treated or you have been told you are at risk of acute glaucoma
- your gut (stomach, intestine or bowel) is or has previously been blocked, perforated or not working properly

- you have or have had ‘ulcerative colitis’ (ulceration and inflammation of the colon) or toxic megacolon (acute dilation of the colon)

- you have or have had an ileostomy or a colostomy.

Do not take Aquiette if any of the above apply to you.

If you are not sure, talk to your pharmacist or doctor before taking Aquiette. **Aquiette is not for use in men.**

Warnings and precautions

Talk to your pharmacist or doctor before taking Aquiette if:

- you currently have one or more of the following signs of urine infections called ‘urinary tract infections’ or UTIs:
 - a temperature or chills (fever)
 - blood in your urine or it looks cloudy or smells bad
 - pain or burning when you pass water
 - pain in your lower back or side
- you have had repeated urinary tract infections (more than 3 in a year)
- you currently have one or more of the following signs, which could be related to a different condition:
 - increased feelings of thirst or tiredness, you frequently need to pass water, infections such as thrush, unexplained weight loss – these can be symptoms of diabetes
 - vaginal pain or dryness, as well as pain or burning when you pass water – this can happen after the menopause and may need other treatment
 - feeling of a bulge or lump in the vagina
 - blood in your water, pain or finding it difficult to pass water
 - feeling bloated all of the time or discomfort in the stomach or pelvic region
 - menstrual bleeding problems such as heavy periods, bleeding between periods or any menstrual bleeding after the menopause

- you have kidney or liver problems
- you have a nerve problem called ‘autonomic neuropathy’ or you have Parkinson’s Disease
- you have an overactive thyroid gland (‘hyperthyroidism’)
- you have high blood pressure
- you have heart problems such as heart failure, or an uneven heart beat (palpitations) or coronary heart disease for example you have had a heart attack

- you have indigestion or heartburn

- you have ‘hiatus hernia’ (where part of your stomach pushes through the diaphragm)

- you will be taking this medicine in a hot climate

- you have or have a history of feeling depressed or anxious, or any other psychiatric illness where you have needed treatment.

If any of the above apply to you (or you are not sure), talk to your pharmacist or doctor before taking Aquiette.

Talk to your pharmacist or doctor immediately if:

- you develop side effects such as confusion, feeling anxious or sleepy, or you are seeing things that are not really there (hallucinations)
- you develop a sudden loss of vision or pain in your eyes, you see haloes around lights, your eyes become red and the pupils become bigger and you have headaches, nausea or vomiting.

Talk to your pharmacist or doctor if:

- Aquiette does not work for you after using it for 6 weeks
- you are still needing to use Aquiette after 12 weeks because you may need a different medicine.

Using this medicine can often reduce the amount of spit (‘saliva’) your body makes, which may cause problems with your teeth and mouth such as tooth decay or oral thrush. Make sure you brush your teeth daily with fluoride toothpaste. Also get regular checkups from your dentist.

Other medicines and Aquiette

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Aquiette may affect some other medicines you take. Also, some other medicines may affect the way Aquiette works. **Do not take Aquiette** if you are already taking any of the following:

- other medicines that have some similar properties with Aquiette that can increase your chances of side effects. ‘Anti-cholinergic or antimuscarinic medicines’ in this group include the following:
 - medicines which can be used to make you feel sleepy (sedatives), or to help with feeling sick (nausea) or vertigo or motion sickness – such as prochlorperazine or chlorpromazine
 - medicines for certain mental illnesses – such as clozapine, phenothiazines or butyrophenones (haloperidol)
 - medicines for depression – such as amitriptyline, nortriptyline or clomipramine (called ‘tricyclic antidepressants’)
 - medicines for allergies (anti-histamines)
 - some cough and cold medicines which may be available without a prescription – check with your pharmacist for advice
 - medicines containing atropine (to slow your heart rate) or medicines like atropine such as dicycloverine or hyoscine (for irritable bowel syndrome)
 - amantadine – used in Parkinson’s disease or for some viral infections
 - L-dopa (levodopa) or procyclidine – for Parkinson’s disease

- medicines used in Alzheimer’s disease called cholinesterase inhibitors such as donepezil, galantamine, rivastigmine as Aquiette may stop them working as effectively
- certain oral antibiotics such as erythromycin or clarithromycin, some oral antifungals such as ketoconazole, some HIV medicines such as ritonavir, or mifepristone used to terminate pregnancy, because these could increase the level of oxybutynin in your blood
- rufinamide used to treat epilepsy as it may stop Aquiette working.

Do not take Aquiette if any of the above apply to you. If you are not sure, talk to your pharmacist or doctor before taking Aquiette.

Aquiette with alcohol

Take care if drinking alcohol while taking Aquiette. This is because Aquiette can make you feel sleepy. Taking them both can make you feel extra sleepy.

Pregnancy and breastfeeding

Do not take Aquiette if you are pregnant, think you may be pregnant or are breastfeeding.

Driving and using machines

You may feel sleepy or have blurred vision while you are taking this medicine, which may be increased by alcohol. If this happens do not drive or use any tools or machines.

Aquiette contains lactose

Aquiette contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take Aquiette

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

How much to take

Take 1 tablet with water 2 or 3 times a day to control your bladder problems. You should try changing your habits and training your bladder for at least 6 weeks before initiating treatment with Aquiette, see 'Bladder Training Plan'. Continue bladder training and habit changes while taking Aquiette.

- Do not take more often than every 6 hours
- Do not take more than 3 tablets each day
- Only take what you need to keep control of your bladder.

After 6 weeks, if your bladder problems are still troublesome, **stop** taking Aquiette and see your doctor because you may need an alternative treatment. If your bladder problems are controlled after taking Aquiette for 6 weeks, then continue with Aquiette and bladder training for another 6 weeks.

If at 12 weeks, your bladder problems are still controlled, stop taking Aquiette and continue with bladder training alone. If after 12 weeks treatment with Aquiette, bladder training alone is not enough to control your bladder problem, stop taking Aquiette and see your doctor because you may need an alternative treatment.

Taking Aquiette

- You can take Aquiette with or without food.
- Swallow the tablet whole, with a glass of water.

If you take more Aquiette than you should

If you take more Aquiette than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine with you so that the doctor knows what you have taken.

Taking too many Aquiette tablets can be dangerous. The following effects may happen:

- feeling very restless or excited
- flushing or feel dizzy or light headed
- very fast, uneven or forceful heartbeat
- breathing problems
- feeling numb
- coma.

If you forget to take Aquiette

If you forget to take a dose when you planned to and you need to be in control of your bladder, take one tablet as soon as you remember. Do not take another tablet until at least 6 hours later.

Do not take a double dose to make up for a forgotten tablet.

If Aquiette does not work for you

Aquiette may not be suitable for some people. Speak to your pharmacist or doctor if:

- your symptoms do not get better or get worse after taking Aquiette
- your symptoms do not get better or get worse within 6 weeks of starting Aquiette
- after 12 weeks treatment, your symptoms are not improved or return after stopping Aquiette
- this medicine has worked for you in the past but no longer controls your symptoms – in some people the bladder may become more overactive as they get older
- you have any further questions on the use of this medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects – stop taking Aquiette and see a doctor or go to hospital straight away if:

- you have an allergic reaction – the signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- you sweat less than usual – this can make you overheat in hot weather
- you have sudden loss of vision or pain in the eye.

Stop taking Aquiette and see a doctor or go to hospital straight away if you notice any of the above.

Other side effects

Tell your pharmacist or doctor if any of the following side effects get serious or last longer than a few days:

- Very common:** may affect more than 1 in 10 people
- dry mouth which can lead to tooth decay, gum disease or oral thrush
- headache
- feeling dizzy or sleepy
- constipation
- feeling sick
- dry skin.

Common: may affect up to 1 in 10 people

- flushing in the face
- diarrhoea
- being sick
- difficulty passing water
- dry eyes
- feeling confused.

Uncommon: may affect up to 1 in 100 people

- loss of appetite
- stomach pain
- difficulty swallowing.

Not known: it is not known how often these side effects happen

- water infection ('urinary tract infection')
- indigestion or heartburn (acid reflux)
- unusual bloating or swelling with pain and feeling sick or being sick (pseudo-obstruction)
- feeling agitated or anxious
- seeing things that are not there (hallucinations), nightmares
- feeling very suspicious and distrustful of others (paranoia)
- depression
- becoming dependent on oxybutynin (the active substance in this medicine)
- fits (convulsions)
- cognitive disorders (i.e. decline in memory function)
- blurred vision, increased pressure in the eyes (glaucoma), large pupils in the eyes
- increased, fast or irregular heartbeat (palpitations)
- heat stroke
- itchy, lumpy rash (urticaria)
- skin that is sensitive to the sun.

Tell your pharmacist or doctor if any of the above get serious or last longer than a few days.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aquiette

Keep this medicine out of the sight and reach of children. Store below 25°C in a dry place. Store in the original package. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of the month.

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

6. Contents of the pack and other information

What Aquiette contains

- The active substance is oxybutynin hydrochloride. One tablet contains 2.5 mg oxybutynin hydrochloride.
- The other ingredients are crospovidone, microcrystalline cellulose, lactose monohydrate, magnesium stearate, indigo carmine aluminium lake (E132).

What Aquiette Tablets look like and contents of the pack

Aquiette Tablets are light blue tablets, marked ^{OXB}2.5 with a scoreline on the reverse and are available in boxes of 28 or 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
MAXWELLIA Ltd, Alderley Park, Alderley Edge, UK, SK10 4TG.

Manufacturer

Niche Generics Limited, Unit 5, 151 Baldoyle Industrial Estate, Dublin 13, Ireland.

This leaflet was last revised in September 2021.

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7. Bladder Training Plan

Before and whilst taking Aquiette to control your symptoms you must try to train your bladder:

- to hold more urine for longer periods of time
- so that it does not need to empty so frequently.

Try at least 6 weeks of bladder training alone to control your symptoms **before** requesting Aquiette from your pharmacist. This is done by gradually increasing the time between the 'got to go' feeling and actually going to the toilet. After a while, the bladder muscle will relax better and you will gain more control.

It is also really important to maintain a healthy diet, avoid being constipated, keep your weight down and do regular pelvic floor muscle exercises.

To train your bladder


Get back in control of your symptoms with this simple bladder training plan:

1. Each time you get the 'got to go' feeling try to hold on for 5 minutes. Do not go to the toilet at the end of the pre-set times unless you still have the need to go. When you do go, make sure you sit down properly on the seat and relax. This will help you to fully empty your bladder each time.
2. When you can hold on for at least 5 minutes after the 'got to go' feeling, increase the hold on time to 15 minutes.
3. When you can hold on for 15 minutes, increase the hold on time by another 10 minutes. Do this until you can last for 3 to 4 hours without having to go to the toilet.
4. Make a note of how often you are going to the toilet to track your progress. The **HoldOn®** App can help you to do this using your mobile device. Download from www.aquiette.co.uk/holdon.


Lifestyle advice

Simple adjustments to lifestyle can make a big difference. Aim to follow the recommendations outlined below, if you aren't already doing so, to help improve the chance of treatment success:


1 • Drink 6 to 8 glasses of water/fluid a day
• Avoid drinks at night



2 • Reduce caffeine, alcohol, fizzy drinks and cigarettes



3 • Keep your pelvic floor muscles fit and strong



More information?

For more help and information visit www.aquiette.co.uk

Don't let your bladder problem put your life on hold. Get back in control and start to overcome your symptoms today.

