

# Oxybutynin hydrochloride

2.5 mg/ 3 mg/ 5 mg tablets

**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. See section 4.

**What is in this leaflet:**

1. What Oxybutynin hydrochloride tablets are and what they are used for
2. What you need to know before you take Oxybutynin hydrochloride tablets
3. How to take Oxybutynin hydrochloride tablets
4. Possible side effects
5. How to store Oxybutynin hydrochloride tablets
6. Contents of the pack and other information

**1. What Oxybutynin hydrochloride tablets are and what they are used for**

Oxybutynin hydrochloride tablets belong to the group of spasm-relieving agents (a so-called spasmolytic).

Oxybutynin hydrochloride tablets act by reducing the muscle spasms of the bladder. It is these spasms that cause the feeling of having to urinate frequently, which in turn can lead to involuntary loss of urine. Oxybutynin relaxes the bladder muscle, so that the bladder can hold more urine and the frequent urge to urinate is reduced.

Oxybutynin hydrochloride tablets may be prescribed by the doctor for the treatment of the involuntary loss of urine as a result of an unstable or over-active bladder. In other words, when it is not possible to keep the urge to urinate and the frequent need to urinate normally under control.

**2. What you need to know before you take Oxybutynin hydrochloride tablets**

**Do not take Oxybutynin hydrochloride tablets**

- if you are allergic to oxybutynin hydrochloride or any of the other 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
- if you have a rare muscle illness called 'Myasthenia gravis'
- if you have glaucoma (increased pressure in the eye, sometimes sudden and painful with blurred vision or loss of vision)
- if your gut (stomach or intestine) is blocked, perforated or not working properly
- if you have a severe form of a condition known as 'ulcerative colitis'
- if you have sudden widening of the colon, which causes abdominal pain, fever or shock known as 'toxic megacolon'
- if you have a blockage that makes it difficult for you to pass water (urine)

Do not take this medicine if any one of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Oxybutynin hydrochloride tablets.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Oxybutynin hydrochloride tablets

- if you have kidney or liver problems
- if you have an illness affecting the nerves called 'autonomic neuropathy' (e.g., Parkinson's disease)
- if you have an overactive thyroid gland (Hyperthyroidism)
- if you have heart disease or high blood pressure
- if you have an irregular heartbeat (palpitations, arrythmias) and/or increased or rapid heartbeat
- if you have an enlarged prostate gland (prostatic hypertrophy)
- if you have gastro-intestinal disorders or disease called ulcerative colitis
- if you have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm), gastro-oesophageal reflux and/or you are using medicinal products that can cause or worsen oesophagitis
- if you have a raised body temperature or fever
- if you will be taking this medicine in a hot climate

Oxybutynin may reduce the amount of saliva resulting in tooth decay or fungal infection of the mouth.

Oxybutynin can cause glaucoma (increased pressure in the eye). Please contact your doctor immediately if you suffer any blurred vision, loss of vision or have any pain in the eye.

Oxybutynin can cause hallucinations, agitation, confusion or somnolence so that your doctor might consider to monitor you.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Oxybutynin hydrochloride tablets.

**Elderly**

People 65 years of age or older should take Oxybutynin hydrochloride tablets with caution, because of the risk of cognitive impairment and being at a greater risk of occurrence of adverse reactions.

**Children**

*Children under 5 years of age*  
The use of Oxybutynin hydrochloride tablets is not recommended in children under 5 years of age.

*Children 5 years of age or older*  
Oxybutynin hydrochloride tablets should be taken with caution as they may be more sensitive to the effects of the product and at a greater risk of occurrence of adverse reactions.

**Other medicines and Oxybutynin hydrochloride tablets**

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This is because Oxybutynin can affect the way some other medicines work. Also, some other medicines can affect the way Oxybutynin works.

In particular, tell your doctor if you are taking any one of the following:

- Other anticholinergic or antimuscarinic medicines such as some medicines for irritable bowel syndrome, asthma or incontinence, motion sickness or movement disorders associated with Parkinson's disease
- Medicines used to make you feel sleepy (sedatives)
- Medicines used to treat nausea and vomiting (prochlorperazine or chlorpromazine)
- Medicines used to treat certain mental illnesses such as clozapine, phenothiazines haloperidol or benperidol (butyrophenones)
- Medicines used to treat dementia e. g. donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors)
- Medicines for depression such as amitriptyline, imipramine or dosulepin ('tricyclic antidepressants')
- Amantadine used in Parkinson's disease or to treat and prevent some virus infections
- L-dopa or biperidin used to treat Parkinson's disease
- Digoxin or quinidine used to treat heart problems
- Atropine which is used to treat certain types of poisonings, a slow heart rate, some eye conditions or is given during surgery
- Medicines for stomach and bowel related problems - such as domperidone, metoclopramide, bethanechol
- Medicines to treat allergic symptoms (antihistamines)
- CYP3A inhibitor e. g. ketoconazole, itraconazole or fluconazole used to treat fungal infections or erythromycin or other macrolide antibiotics used to treat bacterial infections

**Oxybutynin hydrochloride tablets with alcohol**

If you drink alcohol while using Oxybutynin hydrochloride tablets, you may become very drowsy.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

While breast-feeding, small amounts may pass into mothers' milk. Breast-feeding while using this medicine is therefore not recommended.

**Driving and using machines**  
You may feel drowsy or have blurred vision while you are taking this medicine, especially in combination with alcohol. If this happens, do not drive or use any tools or machines.

**Oxybutynin hydrochloride tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Oxybutynin hydrochloride tablets**

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

- Taking this medicine**
- Take this medicine by mouth
  - Swallow the tablets with a glass of water
  - Do not give this medicine to children under 5 years old
  - If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

**The recommended dose is Adults**

You should follow your doctor's instructions closely. In general the dosage will begin with one Oxybutynin hydrochloride 2.5 mg tablet three times daily, later to be increased to a dosage between 10 and 15 mg per day, possibly to a maximum of 20 mg, to be taken in 2 to 3 (maximum 4) doses.

**Elderly**  
The dose must be determined individually for each patient by starting with an initial dosage of 2.5 mg twice daily. Then the lowest possible effective dose should be chosen.

**Children aged 5 years and older**  
The initial dosage is 2.5 mg twice daily. The maximum dosage adjusted to bodyweight (0.3-0.4 mg/kg per day) is given in the table below:

Age	Dosage
5 – 9 years	2.5 mg three times daily
9 – 12 years	5 mg twice daily
older than 12 years	5 mg three times daily

If you feel that the effects of Oxybutynin hydrochloride tablets are too strong or too weak, ask your doctor or pharmacist for advice. Oxybutynin hydrochloride tablets should not be used in children under the age of 5.

**Taking Oxybutynin hydrochloride tablets**

Your doctor will tell you for how long Oxybutynin hydrochloride tablets must be used. It is recommended that the effect should be re-assessed after 4 to 6 weeks, because normal bladder function may have returned.

**Taking Oxybutynin hydrochloride tablets with food or drink**

The tablets should be taken on an empty stomach with plenty of water. If irritation of the stomach occurs, the tablets may be taken during a meal or with some milk.

**If you take more Oxybutynin hydrochloride tablets than you should**

If you take more Oxybutynin hydrochloride tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Oxybutynin hydrochloride tablets can be very dangerous. You may become very restless or excited, flushed or get dizzy or light-headed. Your heartbeat may become very fast, uneven, or forceful or your blood pressure drops. You may get breathing problems or numbness or go into a coma.

**If you forget to take Oxybutynin hydrochloride tablets**

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Oxybutynin hydrochloride tablets**

Keep taking Oxybutynin until your doctor tells you to stop. Do not stop taking Oxybutynin just because you feel better.

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 everyone gets them.

**Stop taking Oxybutynin hydrochloride tablets and see a doctor or go to a hospital immediately if:**

Frequency not known (frequency cannot be estimated from the available data)

- You have an **allergic reaction**, the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You may feel reduced sweating, leading to overheating in hot environments

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

Very common (may affect more than 1 in 10 people)	<ul style="list-style-type: none"><li>- Constipation</li><li>- Nausea</li><li>- Dry mouth</li><li>- Dry skin</li><li>- Headache</li><li>- Somnolence (feeling drowsy or sleepy)</li><li>- Dizziness</li><li>- Blurring of vision</li></ul>
Common (may affect up to 1 in 10 people)	<ul style="list-style-type: none"><li>- Dry eyes</li><li>- Diarrhoea</li><li>- Being sick (vomiting)</li><li>- Flushing especially in children</li><li>- Confusion</li><li>- inability to completely empty the bladder (urinary retention)</li><li>- A forceful heartbeat that may be rapid or irregular</li></ul>
Uncommon (may affect up to 1 in 100 people)	<ul style="list-style-type: none"><li>- Stomach pain</li><li>- Loss of appetite (anorexia)</li><li>- Difficulty in swallowing (dysphagia)</li></ul>
Frequency not known (frequency cannot be estimated from the available data)	<ul style="list-style-type: none"><li>- Increased pressure in the eyes, sometimes sudden and painful with blurred vision or loss of vision (glaucoma)</li><li>- Indigestion or heartburn (acid reflux)</li><li>- Urinary tract infection</li><li>- Heat stroke</li><li>- Difficulty passing water (urine)</li><li>- Agitation</li><li>- Anxiety</li><li>- Becoming dependent on Oxybutynin tablets if there is a history of drug or substance abuse</li><li>- Feeling excessively suspicious and distrustful of others</li><li>- Seeing or hearing things that are not there (hallucinations)</li><li>- Drowsiness</li><li>- Nightmares</li><li>- Fits (convulsions)</li><li>- Depression</li><li>- Increased heartbeat (tachycardia)</li><li>- Irregular heartbeat (arrythmia)</li><li>- Dilatation of pupil (mydriasis)</li><li>- Itchy, lumpy rash (urticaria)</li><li>- Absence of sweating (hypohidrosis)</li><li>- Skin that is more sensitive to the sun (photosensitivity)</li><li>- Disorientation</li><li>- Cognitive disorders</li><li>- Nosebleed</li><li>- Angioedema</li><li>- Muscle weakness, pain or cramps</li></ul>

**Additional side effects in children**

Children are at higher risk of the effects.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the 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 Oxybutynin hydrochloride tablets**

Do not store above 25°C. Store in the original pack.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Always hand over any left-over medicine to the pharmacist for safe disposal.

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 Oxybutynin hydrochloride 2.5 mg / 3 mg / 5 mg tablets contain**

- Each Oxybutynin hydrochloride 2.5 mg Tablet contains 2.5 mg oxybutynin hydrochloride.
- Each Oxybutynin hydrochloride 3 mg Tablet contains 3 mg oxybutynin hydrochloride.
- Each Oxybutynin hydrochloride 5 mg Tablet contains 5 mg oxybutynin hydrochloride.

**The other ingredients are:**  
Crospovidone, microcrystalline cellulose, lactose monohydrate and magnesium stearate.

**What Oxybutynin hydrochloride 2.5 mg / 3 mg / 5 mg tablets look like and contents of the pack**

Oxybutynin hydrochloride is supplied as white circular flat bevelled edge tablets.

Oxybutynin hydrochloride 2.5 mg tablet is marked '2.5' on one side and plain on the other side.

Oxybutynin hydrochloride 3 mg tablet is scored on one side and blank on the other side.

Oxybutynin hydrochloride 5mg tablet is marked '5' on one side and marked with a scoreline on the other side.

The tablets are supplied in blister packs of 7, 28, 56 or 84 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**  
Morningside Healthcare Ltd  
Unit C, Harcourt Way,  
Leicester, LE19 1WP, UK

**Manufacturer**  
FAL Duiven  
Dijkgraaf, 6921, RK Duiven,  
The Netherlands

Morningside Pharmaceuticals Ltd.  
5 Pavilion Way, Loughborough  
LE11 5 GW, UK

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