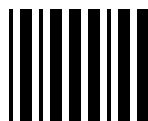


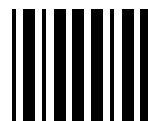
## Oxybutynin Hydrochloride 5mg/5ml Oral Solution

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 Oral Solution is and what it is used for
2. What you need to know before you take Oxybutynin Hydrochloride Oral Solution
3. How to take Oxybutynin Hydrochloride Oral Solution
4. Possible side effects
5. How to store Oxybutynin Hydrochloride Oral Solution
6. Contents of the pack and other information



### 1. What Oxybutynin Hydrochloride Oral Solution is and what it is used for

**What Oxybutynin Hydrochloride Oral Solution is**

Oxybutynin Hydrochloride Oral Solution contains a medicine called oxybutynin hydrochloride. This belongs to two groups of medicines called 'anticholinergics' and 'antispasmodics'.

**How Oxybutynin Hydrochloride Oral Solution works**

It works by relaxing the muscles of the bladder and stops sudden muscle contractions (spasms). This helps control the release of water (urine).

**What Oxybutynin Hydrochloride Oral Solution is used for**

Oxybutynin Hydrochloride Oral Solution can be used in adults and children 5 years or older to treat:

- Loss of control in passing water (urinary incontinence)
- Increased need or urgency to pass water (urine)
- Night time bedwetting, when other treatments have not worked

### 2. What you need to know before you take Oxybutynin Hydrochloride Oral Solution

**Do not take Oxybutynin Hydrochloride Oral Solution:**

- If you are allergic to oxybutynin hydrochloride or any of the other ingredients in 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 of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Oxybutynin Hydrochloride Oral Solution.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Oxybutynin Hydrochloride Oral Solution

Especially be careful if

- you have kidney or liver problems
- you have an illness affecting the nerves called 'autonomic neuropathy' (e.g. Parkinson's disease)
- you have an overactive thyroid gland (Hyperthyroidism)
- you have heart disease or high blood pressure
- you have an irregular heartbeat (palpitations, arrhythmias) and/or increased or rapid heartbeat
- you have an enlarged prostate gland (prostatic hypertrophy)
- you have gastro-intestinal disorders or a disease called ulcerative colitis.
- 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.
- you have a raised body temperature or fever
- 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 apply to you, talk to your doctor or pharmacist before taking Oxybutynin Hydrochloride Oral Solution.

**Elderly**

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

**Children and adolescents**

Children under 5 years of age

Do not give this medicine to children under the age of 5 years.

Children 5 years of age or older

Oxybutynin Hydrochloride Oral Solution 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 Oral Solution**

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

**In particular, tell your doctor if you are taking any 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 with alcohol**

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

**Pregnancy and breast-feeding**

Talk to your doctor before taking this medicine if:

- You are pregnant, think you might be pregnant or are planning to have a baby.
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk. Breast feeding while using oxybutynin is therefore not recommended.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

**Driving and using machines**

You may feel drowsy or have blurred vision while you are taking this medicine. If this happens, do not drive or use any tools or machines.

**Oxybutynin Hydrochloride Oral Solution contains:**

- This medicine contains less than 1 mmol sodium (23 mg) per 5ml that is to say essentially 'sodium-free'
- This medicine contains 5.90mg of sodium benzoate (E211) in each 5ml.
- This medicine contains 1.30g sorbitol in each 5ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect

### 3. How to take Oxybutynin Hydrochloride Oral Solution

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

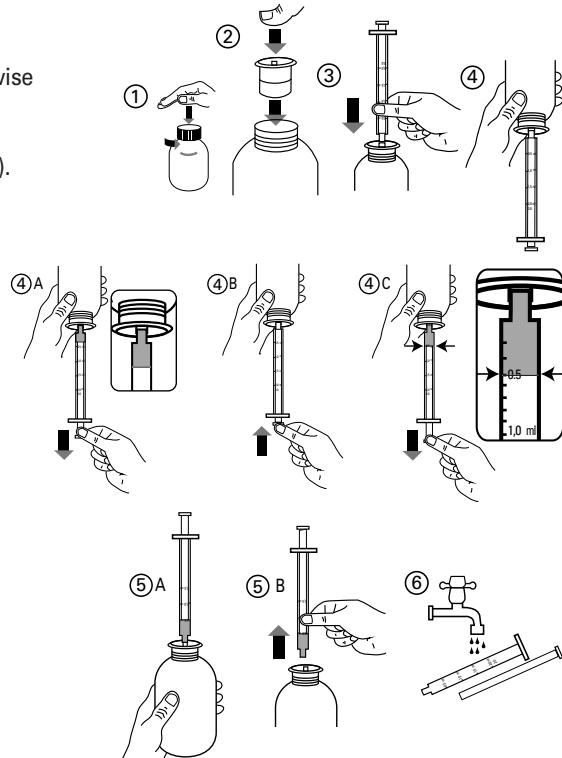
**Taking this medicine**

- Take this medicine by mouth
- Take Oxybutynin oral solution with a glass of water
- Always use the syringe supplied with the pack
- 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

**Measuring your dose**

Instructions for use of the syringe

1. To open the bottle, press the cap down and turn it anti-clockwise (figure 1).
2. Put the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it into the adaptor opening (figure 3).
4. Turn the bottle upside down (figure 4).
5. Fill the syringe with a small amount of solution by pulling the plunger down (figure 4A). Then push the plunger upward in order to remove any possible bubbles (figure 4B). Finally, pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the piston should be in line with the graduation mark you are measuring to (Figure 4C).
6. Turn the bottle the right way up (Figure 5A).
7. Remove the syringe from the adaptor (Figure 5B).
8. Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine (Figure 6).
9. Wash the syringe with water and let it dry before you use it again.
10. Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.


**How much to take**

Your doctor will decide the dose appropriate for you.

**Adults**

- The usual dose is 5mg (5ml) two or three times each day
- Your doctor may decide to increase to the maximum dose of 5mg (5ml) four times each day

**Elderly**

- The usual dose is 2.5mg (2.5ml) twice each day
- Your doctor may decide to increase this to 5mg (5ml) twice each day

**Children (over 5 years)**

- The usual dose is 2.5mg (2.5ml) twice each day
- Your doctor may decide to increase this to 5mg (5ml) two or three times each day
- If you are giving it to a child to prevent bedwetting, give the last dose just before bedtime

**If you take more Oxybutynin Hydrochloride Oral Solution than you should**

If you take more oxybutynin 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 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 Oral Solution**

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 Oral Solution**

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 everybody gets them.

**Stop taking Oxybutynin Hydrochloride Oral Solution and see a doctor or go to a hospital straight away if:**

Frequency unknown

- 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 (affects more than 1 in 10 people)

- Constipation
- Nausea
- Dry mouth
- Dry skin
- Headache
- Somnolence (feeling drowsy or sleepy)
- Dizziness
- Blurring of vision

Common (affects 1 to 10 people in a 100 people)

- Dry eyes
- Diarrhoea
- Being sick (vomiting)
- Confusion
- Flushing especially in children
- Inability to completely empty the bladder (urinary retention)
- A forceful heartbeat that may be rapid or irregular

Uncommon (affects 1 to 10 people in a 1,000)

- Stomach pain
- Loss of appetite (anorexia)
- Difficulty in swallowing (dysphagia)

Frequency not known: frequency cannot be estimated from the available data

- Increased pressure in the eyes sometimes sudden and painful with blurred vision or loss of vision (glaucoma)
- Indigestion or heartburn (acid reflux)
- Urinary tract infection
- Heat stroke
- Difficulty passing water (urine)
- Agitation
- Anxiety
- Becoming dependent on oxybutynin if there is a history of drug or substance abuse
- Feeling excessive suspicious and distrustful of others
- Mental Health disorders (especially in the elderly)
- Seeing or hearing things that are not there (hallucinations)
- Drowsiness
- Nightmares
- Fits (convulsions)
- Depression
- Increased heartbeat (tachycardia)
- Irregular heartbeat (arrhythmia)
- Dilatation of pupil (mydriasis)
- Itchy, lumpy rash (urticaria)
- Absence of sweating (hypohidrosis)
- Skin that is more sensitive to the sun (photosensitivity)
- Disorientation
- Cognitive disorders
- Nosebleed
- Angioedema
- Muscle weakness, pain or cramps

**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, pharmacist or nurse. 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 Oral Solution**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (month, year) which is stated on the label after "EXP". The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original bottle in order to protect from light.
- After first opening of the bottle: Use within 30 days.
- Do not use this medicine if you notice anything wrong with the medicine. Talk to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information****What Oxybutynin Hydrochloride 5mg/5ml Oral Solution contains**

- The active substance is oxybutynin hydrochloride. Each 5ml of the solution contains 5mg oxybutynin hydrochloride.
- The other ingredients are citric acid monohydrate (E330), sodium citrate (E331), sodium benzoate (E211), non-crystallising liquid sorbitol (70%) (E420), glycerol (E422), strawberry flavour, and purified water.

**What Oxybutynin Hydrochloride 5mg/5ml Oral Solution looks like and contents of the pack**

Oxybutynin Hydrochloride Oral Solution is a clear colourless to slightly straw coloured liquid.

It comes in a brown glass bottle holding 150ml of solution with a 5ml purple syringe and bottle adaptor.

**Marketing Authorisation Holder and Manufacturer**

Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

**This leaflet was last revised in 09/2024.**

**If you would like this leaflet in different format information, please contact marketing authorisation holder listed above.**