

Package leaflet: Information for the user

Oxybutynin hydrochloride 2.5mg/5ml oral solution

Oxybutynin hydrochloride

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 symptoms 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
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1. WHAT OXYBUTYNYN HYDROCHLORIDE ORAL SOLUTION IS AND WHAT IT IS USED FOR

What Oxybutynin hydrochloride oral solution is
Oxybutynin hydrochloride 2.5mg/5ml oral solution (called Oxybutynin hydrochloride oral solution in this leaflet) contains a medicine called oxybutynin hydrochloride. This belongs to two groups of medicines called 'anticholinergics' and 'antispasmodics'. 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 OXYBUTYNYN HYDROCHLORIDE ORAL SOLUTION

Do not take Oxybutynin hydrochloride oral solution if you:

- are allergic (hypersensitive) to oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in Section 6)

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

Warnings and precautions

- Talk to your doctor before taking Oxybutynin hydrochloride oral solution, if:**
- you have kidney or liver problems
 - you are 65 years of age or older
 - the person taking the medicine is a child (use is not recommended under 5 years of age)
 - 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
 - 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 hydrochloride may reduce the amount of saliva resulting in tooth decay or fungal infection of the mouth. Oxybutynin hydrochloride 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 hydrochloride oral solution 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.

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 Oxybutynin hydrochloride oral solution to children younger than 5 years of age.

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.

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 - such as prochlorperazine or chlorpromazine or if you are feeling sick (nausea) or have vertigo
- Medicines used to treat certain mental illnesses - such as clozapine, phenothiazines, haloperidol or benperidol (butyrophenones)
- Medicines to treat dementia - e.g. donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors)
- Medicines for depression - such as amitriptyline, imipramine or doxepin ("tricyclic antidepressants")
- Amantadine - used in Parkinson's disease or to treat and prevent some virus infections
- Levodopa or biperiden - 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
- Domperidone, metoclopramide, bethanechol, medicines for stomach and bowel related problems
- Medicines to treat allergic symptoms (antihistamines)
- CYP3A inhibitors e.g. ketoconazole, itraconazole or fluconazole used to treat fungal infections or erythromycin or other macrolide antibiotics used to treat bacterial infections.

Oxybutynin hydrochloride oral solution with alcohol
If you drink alcohol while using Oxybutynin hydrochloride oral solution, you may become drowsy.

Pregnancy, breast-feeding and fertility
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. Small amounts of Oxybutynin hydrochloride may pass into mothers' milk. Breast feeding while using Oxybutynin hydrochloride is therefore not recommended.

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.

Important information about some of the ingredients of Oxybutynin hydrochloride oral solution

- This medicine contains:
- **Sorbitol:** Oxybutynin hydrochloride oral solution contains 125 mg sorbitol in each ml which is equivalent to 625 mg per dose of 5 ml. 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.
 - **Maltitol:** Oxybutynin hydrochloride oral solution contains 125 mg maltitol in each ml which is equivalent to 625 mg per dose of 5 ml. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
 - **Methyl parahydroxybenzoate:** It may cause allergic reactions (this may not happen straightaway). Signs of an allergic reaction include: rash, problems swallowing or breathing, swelling of the lips, face or throat.
 - **Propylene glycol:** Oxybutynin hydrochloride oral solution contains 1.47 mg propylene glycol in each ml which is equivalent to 7.35 mg per dose of 5 ml.
 - **Sodium:** Each dose (5 ml) of the medicine contains less than 23 mg of sodium; it is therefore considered sodium free.
 - **Ethanol (alcohol):** This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per 5 ml. Talk to your pharmacist or doctor if you need Oxybutynin hydrochloride oral solution on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. HOW TO TAKE OXYBUTYNYN HYDROCHLORIDE ORAL SOLUTION

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

- **For oral use only.** Take this medicine by mouth.
- Shake the bottle before use
- Use the measuring cup provided (marked in 5ml and 10ml graduations)
- Do not give this medicine to children under 5 years old.

How much to take
Your doctor will decide the dose appropriate for you.

- Adults**
- The usual dose is 5mg (10ml) two or three times each day
 - Your doctor may decide to increase to the maximum dose of 5mg (10ml) four times each day.

- Elderly**
- The usual dose is 2.5mg (5ml) twice each day
 - Your doctor may decide to increase to the maximum dose of 5mg (10ml) twice each day.

- Children (over 5 years)**
- The usual dose is one 2.5mg (5ml) twice each day
 - Your doctor may decide to increase this to 5mg (10ml) 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 hydrochloride oral solution than you should, or if you think a child has accidentally swallowed any, tell a doctor or go to a hospital casualty department straight away. Take this leaflet with you. This is so the doctor knows what you have taken.

Taking too much Oxybutynin hydrochloride can be very dangerous. You may become very restless or excited, flushed or get dizzy or light-headed. Your heart beat may become very fast, uneven or forceful. 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 the next dose as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

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

If you stop taking Oxybutynin hydrochloride oral solution
Keep taking Oxybutynin hydrochloride oral solution until your doctor tells you to stop. **Do not stop taking Oxybutynin hydrochloride oral solution just because you feel better.**

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Children are at higher risk of the effects.

Stop taking Oxybutynin hydrochloride oral solution and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, problems swallowing or breathing, swelling of your lips, face, throat or tongue
- You may feel reduced sweating, which can lead 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)**
- Constipation
 - Nausea
 - Dry mouth
 - Dry skin
 - Headache
 - Somnolence (feeling drowsy or sleepy)
 - Dizziness
 - Blurring of vision.

- Common (affects between 1 in 10 and 1 in 100 people)**
- Dry eyes
 - Diarrhoea
 - Being sick (vomiting)
 - Confusion
 - A forceful heartbeat that may be rapid or irregular especially in children
 - Inability to completely empty the bladder (urinary retention).

- Uncommon (affects between 1 in 100 and 1 in 1,000 people)**
- Stomach pain
 - Loss of appetite (anorexia)
 - Difficulty in swallowing (dysphagia).

Frequency unknown

- 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 hydrochloride (if there is a history of drug or substance abuse)
- Feeling excessively 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 heart beat (tachycardia)
- Irregular heart beat (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 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 OXYBUTYNYN HYDROCHLORIDE ORAL SOLUTION

Do not store above 25°C. Keep this medicine out of the sight and reach of children. Once opened use within one month. Store in the original packaging.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month. Do not dispose of 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 oral solution contains
Each 5ml of oral solution contains 2.5 mg of the active substance oxybutynin hydrochloride.

The other ingredients are: Sorbitol (E420), maltitol (E965), glycerol (E422), xanthan gum, methyl parahydroxybenzoate (E218), citric acid monohydrate, sodium citrate dihydrate, strawberry flavour (contains propylene glycol (E1520)), citric acid solution, ethanol and purified water.

What Oxybutynin hydrochloride looks like and contents of the pack
Oxybutynin hydrochloride oral solution is a strawberry flavoured clear, colourless solution.

Oxybutynin hydrochloride oral solution is packed in amber, type III 150ml glass bottles sealed with a child-resistant, tamper-evident screw cap. It comes with a 15ml measuring cup with 5ml and 10ml graduations.

Marketing Authorisation Holder and Manufacturer

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