

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Oxybutynin Hydrochloride 3mg Tablets

**Read all of this leaflet carefully before
you start taking this medicine**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What oxybutynin is and what it is used for
2. Before you take oxybutynin
3. How to take oxybutynin
4. Possible side effects
5. How to store oxybutynin
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1. What oxybutynin is and what it is used for



What oxybutynin is

The name of your medicine is Oxybutynin Hydrochloride 3mg Tablets (referred to as oxybutynin throughout this leaflet). It contains a medicine called oxybutynin hydrochloride. This belongs to two groups of medicines called 'anticholinergics' and 'antispasmodics'.

How oxybutynin 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 is used for

- Oxybutynin 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. Before you take oxybutynin

**✗ Do not take this medicine and tell
your doctor if:**

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

Signs of an allergic reaction include:
a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

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

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



**Take special care with oxybutynin.
Check with your doctor or pharmacist
before taking your medicine if:**

- ▲ You have kidney or liver problems
- ▲ You are 65 years of age or older
- ▲ The person taking this medicine is a child (use is not recommended under 5 years of age)
- ▲ You have an illness affecting the nerves called 'autonomic neuropathy'
- ▲ You have an overactive thyroid gland ('Hyperthyroidism')
- ▲ You have heart disease or high blood pressure

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- ▲ You have an irregular heart beat (palpitations) and/or increased or rapid heart beat
- ▲ You have an enlarged prostate gland
- ▲ You have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm)
- ▲ You have a raised body temperature or fever
- ▲ You will be taking this medicine in a hot climate

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

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



Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal 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 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) or if you are feeling sick (nausea) or have vertigo – such as prochlorperazine or chlorpromazine
- Medicines used to treat certain mental illnesses such as clozapine, phenothiazines haloperidol or benperidol (butyrophenones)
- 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 – used to treat Parkinson's disease
- Digoxin – used to treat heart problems.
- Medicines for stomach and bowel related problems - such as domperidone, metoclopramide or bethanechol

Pregnancy and breastfeeding

Talk to your doctor before taking this medicine if

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast feed. This is because small

amounts may pass into mothers' milk. Breastfeeding 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.

Important information about some of the ingredients of oxybutynin

This medicine contains:

- **Lactose:** If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take oxybutynin

Always take oxybutynin exactly as your doctor has told you. You should 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.

How much to take

Your doctor will decide the dose appropriate for you.

Adults

- The usual starting dose is one 5mg oxybutynin tablet two or three times each day
- Your doctor may decide to increase to the maximum dose of 5mg four times each day

Elderly

- The usual starting dose is one 3mg tablet twice each day
- Your doctor may decide to increase this until you respond to the medicine

Children (over 5 years)

- The starting dose is one 3mg tablet twice each day
- The usual dose is then one 5mg tablet twice each day
- Your doctor may decide to increase this to one 5mg tablet 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 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, flush or get dizzy or lightheaded.

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

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

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

4. Possible side effects

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

Stop taking oxybutynin 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 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
- Dry mouth

- Feeling sick, being sick
- Dry skin
- Headache
- Somnolence (feeling drowsy or sleepy)
- Dizziness
- Blurring of vision

Common (affects 1 to 10 people in a 100)

- Dry eyes
- Diarrhoea
- Vomiting
- Flushing especially in children
- Confusion
- 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 unknown

- Increased pressure in the eyes, sometimes sudden and painful with blurred vision or loss of vision (glaucoma), enlargement of the pupil of the eye
- Indigestion or heartburn (acid reflux)
- Urinary tract infection
- Increased, rapid or irregular heartbeat
- Heat stroke
- Difficulty passing water (urine)
- Agitation
- Anxiety
- Becoming dependent on Oxybutynin
- Feeling excessively suspicious and distrustful of others (paranoia)
- Seeing or hearing things that are not there (hallucinations)
- Drowsiness
- Nightmares

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- Fits (convulsions)
- Depression
- Itchy, lumpy rash (urticaria)
- Absence of sweating (hypohidrosis)
- Skin that is more sensitive to the sun (photosensitivity)
- Abnormal bloating/swelling together with pain and feeling or being sick (pseudo-obstruction)

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store oxybutynin

Keep this medicine in a safe place where children cannot see or reach it.

Do not use oxybutynin after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Medicines should not be disposed of 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. Further Information

What Oxybutynin 3mg Tablets contain

- Each tablet contains 3mg of the active substance oxybutynin hydrochloride
- The other ingredients are lactose, microcrystalline cellulose, calcium stearate and indigo carmine aluminium lake (E132)

What oxybutynin looks like and contents of the pack

- Oxybutynin 3mg Tablets are pale blue round tablets with OXB3 on one side. Supplied in blisters of 56 tablets.

Marketing Authorisation Holder and Manufacturer

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Zentiva Pharma UK Limited,
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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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