

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Oxybutynin Hydrochloride 2.5mg and 5mg 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 of the 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 is and what it is used for
2. What you need to know before you take Oxybutynin
3. How to take Oxybutynin
4. Possible side effects
5. How to store Oxybutynin
6. Contents of the pack and other information

1. What Oxybutynin is and what it is used for

Oxybutynin hydrochloride belongs to a group 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 urine.

Oxybutynin Tablets can be used in **adults** to treat the following:

- Loss of control in passing urine (urinary incontinence)
- Increased need or urgency to pass urine

Oxybutynin Tablets can be used in **children 5 years or older** to treat the following:

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

2. What you need to know before you take Oxybutynin

Do not take if:

- You are allergic to oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- Your gut (stomach or intestine) is blocked, perforated or not working properly
- You have a form of inflammatory bowel disease which can cause abdominal pain, bloody diarrhoea, fever and weight loss (severe ulcerative colitis) or sudden widening of the colon, which causes abdominal pain, fever or shock (toxic megacolon)
- You have a blockage which makes it difficult to pass urine
- You have a muscle weakness illness (myasthenia gravis)
- You have increased pressure in the eye, sometimes sudden and painful with blurred vision or loss of vision (glaucoma)
- You have difficulty passing urine

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxybutynin if:

- You have liver or kidney problems
- You have obstructions of the stomach or intestines
- You have indigestion or heart burn caused by a 'hiatus hernia' (where part of the stomach pushes through the diaphragm)
- You are taking medicines to treat osteoporosis (known as bisphosphonates)
- You have damaged nerves, which can affect the way internal organs work (autonomic neuropathy)

- You will be taking this medicine in a hot climate as Oxybutynin can decrease your ability to sweat and may cause fever or heat stroke
- You have an overactive thyroid gland (hyperthyroidism)
- You have heart disease or heart failure
- You have high blood pressure
- You have an irregular, increased or rapid heart beat
- You are elderly, frail (weak or in poor health) or have Parkinson's disease, as you may be more prone to experiencing side effects
- Oxybutynin may reduce the amount of saliva resulting in tooth decay or fungal infection of the mouth

Children and adolescents

In children over 5 years of age, Oxybutynin hydrochloride should be used with caution as they may be more sensitive to the effects of the product, particularly the Central Nervous System and psychiatric adverse reactions.

The use of Oxybutynin in children under 5 years of age is not recommended.

Other medicines and Oxybutynin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without prescription. This includes herbal medicines.

Medicines which **may interact with or be affected by** Oxybutynin:

- Atropine, used to treat certain types of poisonings, a slow heart rate, to decrease saliva production during surgery and some eye conditions
- Other anticholinergic medicines, such as some medicines for irritable bowel syndrome, asthma, incontinence, motion sickness or movement disorders associated with Parkinson's disease
- Amantadine, used for Parkinson's disease or to treat and prevent some virus infections
- Levodopa or biperiden, used to treat Parkinson's disease
- Antihistamines, medicines used to relieve symptoms of allergies and reactions
- Phenothiazines, butyrophenones and clozapine (anti-psychotics), used to treat mental illness
- Digitalis or quinidine, used to treat heart conditions
- Tricyclic anti-depressants, used to treat depression e.g. amitriptyline, imipramine, dosulepin
- Dipyridamole, used to treat blood clotting problems
- Medicines used to treat dementia e.g. donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors)

Taking Oxybutynin with alcohol

If you drink alcohol while taking these tablets, you may become very drowsy.

Pregnancy and breastfeeding

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

Pregnancy

If you are pregnant or think you are pregnant; you should not take this medicine unless your doctor tells you to.

Breastfeeding

If you are breast-feeding you should not take this medicine as small amounts may pass in to your milk.

Driving and using machines

You may feel drowsy or have blurred vision whilst taking Oxybutynin. If this happens, do not drive or operate machinery.

Oxybutynin contains lactose

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

3 How to take Oxybutynin

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

- These tablets are for oral use.
- The tablets should be swallowed with water.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole and not to divide into equal doses.

Adults:

- The usual dose is 5mg taken two or three times a day.
- This may be increased to a maximum dose of 5mg four times a day.

Elderly (including frail elderly):

- The usual dose is 2.5mg twice a day.
- This dose may be increased to 5mg twice a day.

Use in children (over 5 years):

- The usual dose is 2.5mg taken twice a day.
- This dose may be increased to 5mg two or three times a day.
- If you are giving it to a child to prevent urgency and frequency to pass urine or bedwetting, give the last dose just before bedtime.

Use in children (under 5 years):

This medicine is **not recommended**.

If you have taken more Oxybutynin than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: feeling restless or excited, behaviour changes, flushing, feeling dizzy or light-headed (due to a fall in blood pressure), heart problems, difficulty breathing, being unable to move your body (paralysis) and loss of consciousness (coma).

If you forget to take your Oxybutynin

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Oxybutynin

It is important that you keep taking Oxybutynin for as long as your doctor has told you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Oxybutynin can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)

Very common side effects (may affect more than 1 in 10 people)

- Constipation
- Dry mouth
- Feeling sick (nausea)
- Headache
- Dizziness
- Feeling drowsy or sleepy (somnolence)
- Blurred vision
- Dry skin

Common side effects (may affect up to 1 in 10 people)

- Diarrhoea

- Being sick (vomiting)
- Confusion
- Dry eyes
- Difficulty passing urine
- Flushing of the face (especially in children)
- A forceful heartbeat that may be rapid or irregular

Uncommon side effects (may affect up to 1 in 100 people)

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

Other side effects (frequency not known)

- Urinary tract infection
- Indigestion or heart burn (acid reflux)
- Feeling agitated
- Anxiety
- Seeing or hearing things that are not real (hallucinations)
- Nightmares
- Unfounded or excessive fears about others (paranoia)
- Impaired brain function, particularly in the elderly (e.g. memory loss, forgetfulness, confusion)
- Depression
- Dependence on Oxybutynin (in patients with a history of dependency)
- Drowsiness
- Fits (convulsions)
- Not knowing where you are (disorientation)
- Faster heartbeat (tachycardia)
- Irregular heartbeat (arrhythmia)
- Nose bleeds (epistaxis)
- Heat stroke
- Enlargement of the pupil (mydriasis)
- Increased eye pressure (ocular hypertension)
- Eye pain, red eyes and reduced vision caused by pressure inside the eye rising (angle closure glaucoma)
- Delay or difficulty passing urine
- Skin rashes with the formation of wheals (urticaria)
- Reduced sweating (hypohidrosis)
- Increased sensitivity of eyes and skin to sunlight (photosensitivity)
- Muscle disorders such as muscle weakness, muscle pain (myalgia) and/or muscle spasms

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 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

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the carton/blister packaging after EXP. The expiry date refers to the last day of that month.
- Store in the original package below 25°C, in a dry place.
- Medicines should not be disposed of 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 Tablets contains:

- Each 2.5mg tablet contains 2.5mg of oxybutynin hydrochloride
- Each 5mg tablet contains 5mg of oxybutynin hydrochloride

The other ingredients are: crospovidone, microcrystalline cellulose, lactose monohydrate, magnesium stearate and indigo carmine aluminium lake (E132).

What Oxybutynin Tablets look like and the contents of the pack:

- Oxybutynin 2.5mg are light blue, circular flat bevelled edged tablet with an approximate diameter of 6 mm, marked OXB 2.5 on one side and a break line on reverse.
- Oxybutynin 5mg are light blue, circular flat bevelled edged tablet with an approximate diameter of 7.5 mm, marked OXB 5 on one side and a break line on reverse.

Oxybutynin Tablets are available in:

Oxybutynin tablets are available in packs of 20, 28, 30, 56, 60, 84 or 120 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

- Oxybutynin Hydrochloride 2.5mg Tablets - PL 11311/0136
- Oxybutynin Hydrochloride 5mg Tablets - PL 11311/0137

Marketing Authorisation Holder & Manufacturer:

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

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