



PACKAGE LEAFLET:
INFORMATION FOR THE USER

**OXYBUTYNIN HYDROCHLORIDE
TABLETS 2.5 mg and 5 mg**

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 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 contain an active ingredient called Oxybutynin hydrochloride. This belongs to two groups of medicines called "anticholinergics and "antispasmodics". This medicine relaxes and prevents spasms (contractions) of the muscle of the bladder, and helps to control the release of urine.

Oxybutynin Hydrochloride Tablets are used to treat the following in adults:

- Loss of control in passing urine (urinary incontinence)
- Increased need or urgency to pass urine
- Problems passing urine due to multiple sclerosis and spina bifida.

Oxybutynin Hydrochloride Tablets can be used in children 5 years and older to treat:

- 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 HYDROCHLORIDE TABLETS

Do not take Oxybutynin Hydrochloride Tablets if you:

- Are allergic to oxybutynin hydrochloride or any of the ingredients of this medicine, (listed in Section 6)
- Have myasthenia gravis (muscle weakness)
- Suffer with glaucoma (high pressure and pain in the eyes)
- Have diseases of the intestine (gut) including obstructions of the bowel
- Have toxic megacolon (dilated colon accompanied by fever and abdominal pain)
- Have undergone surgeries like ileostomy or colostomy (surgical opening in the abdominal wall)
- Have severe ulcerative colitis (a form of inflammatory bowel disease)
- Have a blocked urinary tract causing a poor flow of urine
- Have porphyria which is a disorder of the skin and nervous system
- Have frequent urination at night caused by heart or kidney disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxybutynin Hydrochloride Tablets if you suffer from:

- Diseases of the nervous system (autonomic neuropathy) such as those with Parkinson's disease
- Liver or kidney problems
- Severe diarrhoea or constipation
- An overactive thyroid (hyperthyroidism)
- Heart disease, heart failure, a fast or irregular heart beat
- Cognitive disorders such as amnesia, dementia, and delirium
- An enlarged prostate gland
- Diseases of the oesophagus (food pipe) including a hiatus hernia, or if you are taking medicines (e.g. bisphosphonates) that could worsen oesophagitis (inflamed oesophagus)

- Heart disease or high blood pressure
- A fever or are in a hot environment as Oxybutynin Hydrochloride Tablets may reduce the amount you sweat and this may increase your chance of heat stroke.

Check with your doctor or pharmacist before taking this medicine if:

- The person taking this medicine is a child (use is not recommended under 5 years of age).
- You are 65 years of age or older

Reduced saliva due to Oxybutynin Hydrochloride Tablets may increase dental caries or oral infection. Regular dental check-ups are advisable during long-term treatment.

If you notice vision changes or suffer from any pain in the eye whilst using Oxybutynin Hydrochloride Tablets tell your doctor who may do a vision test.

Oxybutynin Hydrochloride Tablets may affect your central nervous system. If you have hallucinations, agitation, confusion or sleepiness you should tell your doctor.

Other medicines and Oxybutynin Hydrochloride Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially any of the following:

- Other medicines to treat urinary disorders such as propiverine or tolterodine
- Any other medicines which act in the same way as Oxybutynin, these are called anticholinergic medicines. Examples include atropine used in glaucoma, hyoscine for nausea
- Medicines to stop vomiting such as phenothiazines (e.g. prochlorperazine), metoclopramide and domperidone
- Medicines to treat Parkinson's disease such as amantadine, levodopa or benzotropine mesylate
- Medicines called anticholinesterases used for Alzheimer's disease (e.g. memantine)
- Medicines to treat heart conditions such as digitalis (digoxin)
- Antihistamines used for allergies
- Medicines to treat psychotic disorders including schizophrenia such as butyrophenones (e.g. benperidol) or clozapine
- Medicines used to correct disturbances in the rhythm of the heart such as Quinidine
- Medicines called Monoamine Oxidase Inhibitors (MAOIs) or tricyclic antidepressants used to treat depression (e.g. Isocarboxazid and moclobemide)
- Medicines to prevent blood clots such as dipyridamole
- Medicines to treat fungal infections (ketoconazole, itraconazole or fluconazole)
- Medicines to treat bacterial infections (erythromycin or other macrolide antibiotics).

Oxybutynin Hydrochloride Tablets and alcohol

These tablets can cause drowsiness which may be enhanced if you consume alcohol.

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. Your doctor will decide whether you need to take this medicine during pregnancy and whether it is safe to do so. You should not breast-feed whilst taking oxybutynin as it passes into your milk.

Driving and using machines:

As Oxybutynin Hydrochloride Tablets may cause drowsiness or blurred vision in some people, do not drive or operate machinery, if affected.

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

Oxybutynin Hydrochloride Tablets contain Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'.

3. HOW TO TAKE OXYBUTYNIN HYDROCHLORIDE TABLETS

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

The recommended dose is



180 x 312 mm

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ARTWORK DETAIL LABEL

Product	Oxybutynin Hydrochloride 2.5mg / 5mg			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	180 x 312 mm	Pack	----	
New Item Code	1047065	Old Item Code	1037254	
Colour Shades	■ Black	No. of Colours	1	
Change Control No.	PC-TSG/2022/046 - Record Number: 333148		Artwork Version	7.0
Design/Style	Front & Back Printing. To be supplied in unfolded size			
Substrate	60 GSM Paper			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

Adults

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

Elderly

Initially 2.5mg twice a day increased to 5mg twice a day according to response.

Use in children (over 5 years) and adolescents**Urinary incontinence:**

The usual dose is 2.5mg twice a day. This may be increased to 5mg two or three times a day.

Bed wetting:

The usual dose is 2.5mg twice a day, increased to 5mg two or three times a day, with the last dose given before bedtime.

Children under 5 years

Not recommended.

Swallow the tablet whole with a glass of water.

The dose recommendations given above are a guideline only. Your doctor may prescribe a different dose.

If you take more Oxybutynin Hydrochloride Tablets than you should:

An overdose of this medicine may be harmful. Symptoms of overdose include restlessness, excitement, abnormal behaviour, flushing, fall in blood pressure, problems with your circulation, breathing problems, paralysis and coma. If you or someone else, have taken too much of your medicine tell your doctor or pharmacist, or go to the nearest hospital casualty department immediately. Take the medicine pack with you, to inform the doctor what you have taken.

If you forget to take Oxybutynin Hydrochloride Tablets:

If you forget to take a dose at the right time, take it as soon as you remember, then go on as before. However you must take care not to take two doses at the same time.

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

If you stop taking Oxybutynin Hydrochloride Tablets

Do not stop or change the treatment before talking to your doctor as desired effect of the medicine may not be achieved.

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.

Allergic reactions:

If you experience an allergic reaction which may include symptoms such as swelling of the face, neck, throat or body, a rash which may be itchy, swallowing or difficulty breathing; stop taking the tablets and **contact your doctor immediately**.

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/decreased sweating
- Headache
- Somnolence (feeling drowsy or sleepy)
- Dizziness
- Blurring of vision
- Decreased tear production/dry eyes
- Facial flushing especially in children
- Difficulty emptying the bladder (Urinary retention)

Common (affects 1 to 10 people in 100 people)

- Diarrhoea
- Indigestion
- Being sick (vomiting)
- Confusion

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

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

Rare (may affect up to 1 in 1,000 people)

- Restlessness
- Erectile dysfunction
- Disorientation, difficulties in concentration
- Skin that is more sensitive to the sun (photosensitivity).

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)
- Excitation
- Agitation
- Anxiety
- Becoming dependent on Oxybutynin Hydrochloride Tablets
- Feeling excessively suspicious and distrustful of others
- Mental Health disorders
- Seeing or hearing things that are not there (hallucinations)
- Nightmares
- Fits (convulsions)
- Depression
- Increased heart beat (tachycardia)
- Irregular heart beat (arrhythmia)
- Dilation of pupil (mydriasis)
- Itchy, lumpy rash (urticaria)
- Absence of sweating (hypohidrosis)
- Severe impairment in the ability of the intestines to push food through (pseudo-obstruction)
- Paranoia
- Cognitive disorders in elderly
- Cognitive dysfunction
- Narrow angle closure glaucoma
- Ocular hypertension
- Angioedema
- Rash (allergic reaction).

If you get any of these side effects, please consult your doctor as he may decrease your dose to reduce the effects.

The following may be detected in blood tests performed by your doctor

- Changes in the number blood cells or platelets
- Increased blood sugar
- Increase or decrease in blood pressure
- Inflammation of a vein under the skin
- Changes in the hormone, chemical and enzyme levels in the body.

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 OXYBUTYNIN HYDROCHLORIDE TABLETS

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label.

The expiry refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Oxybutynin Hydrochloride Tablets contain**

The active substance(s) is Oxybutynin Hydrochloride/ Oxybutynin Chloride BP/Ph.Eur.

The other ingredients are: Lactose monohydrate, Microcrystalline cellulose, Calcium stearate, Indigo carmine (aluminium lake) E132

What Oxybutynin Hydrochloride Tablets look like and contents of the pack

Description: Oxybutynin Hydrochloride Tablets 2.5 mg: Blue, biconvex, uncoated capsule-shaped tablets, marked "OB" scoreline "2.5" on one side and plain on the other side. Oxybutynin Hydrochloride Tablets 5 mg: Blue, round, biconvex, uncoated tablets, marked "OB" breakline "5" on one side and plain on the other side.

Contents of pack: Blister pack containing 56 or 84 tablets. 7 tablets in a blister, 8 or 12 blisters in a carton.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, Metro Centre,
Tolpits Lane, Watford, Herts.,
UK, WD18 9SS

This leaflet was last revised in May 2022.



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