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Prepared By Regulatory Affairs		Checked By Regulatory Affairs		Approved By Quality Assurance



Package leaflet: Information for the user

## Oxybutynin hydrochloride 2.5 mg tablets Oxybutynin hydrochloride 5 mg tablets

### 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. See section 4.

#### What is in this leaflet

1. What Oxybutynin Tablets are and what they are used for
2. What you need to know before you take Oxybutynin Tablets
3. How to take Oxybutynin Tablets
4. Possible side effects
5. How to store Oxybutynin Tablets
6. Contents of the pack and other information

### 1. What Oxybutynin Tablets are and what they are used for

Oxybutynin Tablets 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).

Oxybutynin Tablets can be used to treat:

Adults:

Frequent and severe urinary urgency or Loss of control in passing urine (urge incontinence).

Children over 5 years:

- Loss of control in passing water (urinary incontinence).
- Increased need or urgency to pass urine (frequent and excessive urination).
- Night time bedwetting in children when other treatments have not worked.

### 2. What you need to know before you take Oxybutynin Tablets

**Do not take Oxybutynin Tablets and tell your doctor if:**

- You are allergic to Oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in Section 6).
- You have a rare condition called “Myasthenia gravis” that makes the muscles in the body become weak and tire easily.
- You have increased pressure in the eye (glaucoma).
- Your gut (stomach or intestine) is blocked, perforated or not working properly
- You have a severe form of a condition known as “ulcerative colitis (inflammatory disease of the large intestine)”.
- You have a blockage that makes it difficult for you to pass water (urine).
- You have frequent urination at night caused by heart or kidney disease

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

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Oxybutynin Tablets if:

- You have kidney or liver problems
- You are 65 years of age or older
- The person taking the medicine is a child
- 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
- You have an irregular heart beat (palpitations) and/or increased or rapid heart beat
- You have an enlarged prostate gland
- You have gastro-intestinal disorders
- You have indigestion or heart burn caused by a “ hiatus hernia” (where part of your stomach pushes through the diaphragm
- You have raised body temperature or fever
- You will be taking this medicine in hot climate
- You are taking medicines called bisphosphonates, which are used to treat bone diseases

Please contact a physician immediately if you experience a sudden loss of visual acuity or ocular pain.

Prolonged use may result in an increase in dental caries, as a consequence of reduced or suppressed salivary secretions. Regular dental check-ups are therefore advisable during long-term treatment. The ability of sublingual tablets to melt under the tongue may deteriorate due to dry mouth. You should moisten the mouth with the tongue or with a little water before taking sublingual tablets.

#### Children

*Children below 5 years of age*

Oxybutynin hydrochloride is not recommended for use in children below 5 years

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

#### Other medicines and Oxybutynin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Oxybutynin may slow the digestive tract and thereby influence the effect of other medicines, or the use of this medicine together with other medicines may increase the effect of oxybutynin. In particular, tell your doctor if you are taking any one of the following:

- Atropine, compounds related to atropine (used for treatment of cramps) and other anticholinergic medicines (used for treatment in stomach disorders such as irritable bowel syndrome)
- Prochlorperazine or chlorpromazine (phenothiazines), Clozapine or other antipsychotics (Medicines used to treat psychosis).
- haloperidol or beneridol (butyrophenones) (Medicines used to treat certain mental illness)
- amitriptyline, imipramine or dosulepin or tricyclic anti depressants (Medicines used to treat depression)
- Amantadine (used in Parkinson’s disease or to treat and prevent some virus infections)
- Levodopa, biperiden (used to treat Parkinson’s disease)
- Digoxin (used to treat heart problems)
- Dipyridamole (used to treat blood clotting problems).
- Ketoconazole, itraconazole or fluconazole (used for the treatment of fungal infections).
- Erythromycin a macrolide antibiotic (used to treat bacterial infections).
- Quinidine (used to treat heart problems)
- Anti-histamines
- Metoclopramide and domperidone (used to treat nausea and vomiting)
- Cholinesterase inhibitors

#### Oxybutynin Tablets with alcohol

Oxybutynin may cause drowsiness or blurred vision. Drowsiness may be increased by consumption of 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 as oxybutynin should not be used during pregnancy unless clearly necessary

When oxybutynin is used during breast-feeding, a small amount is excreted in the mother’s milk. Use of oxybutynin while breast-feeding 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.

#### Oxybutynin Tablets contains lactose

Oxybutynin Tablets contains lactose. If you have intolerance to some sugars, consult your doctor before taking this medicine.

### 3. How to take Oxybutynin Tablets

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

#### *The recommended dose is*

##### Adults

- An initial dose of 2.5 mg three times daily.
- Your doctor may decide to increase to the maximum dose of 5mg four times daily

##### Elderly

- An initial dose is 2.5 mg twice daily
- Your doctor may decide to increase this to 5 mg twice daily

##### Children (over 5 years)

- An initial dose is 2.5 mg twice daily
- Your doctor may decide to increase this to 5 mg two or three times daily
- If you are giving it to a child to prevent bedwetting, give the last dose just before bedtime

Swallow the tablet whole with a glass of water.

Do not change the dose yourself, inform your doctor if you feel the effect of your medicine too weak or too strong.

#### If you take more Oxybutynin Tablets than you should

If you take more Oxybutynin Tablets than you should, tell a doctor or go to a hospital casualty department immediately. Take the medicine pack with you, to inform the doctor what you have taken.

Taking too many Oxybutynin Tablets 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 Tablets

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 Tablets

Keep taking Oxybutynin Tablets until your doctor tells you to stop. Do not stop taking Oxybutynin Tablets 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 Tablets and see a doctor or go to a hospital immediately if:

- You have an allergic reaction, the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

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**Tel 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)

- dizziness, headache, somnolence (feeling drowsy or sleepy)
- decreased tear production/dry eyes
- facial flushing (especially in children)
- constipation
- nausea
- dry mouth
- dry skin/decreased sweating
- urinary retention

Common (may affect up to 1 in 10 people)

- indigestion, diarrhoea, being sick (vomiting)
- confusion

Uncommon (may affect up to 1 in 100 people)

- loss of appetite (anorexia)
- drowsiness,
- stomach pain
- difficulty in swallowing (dysphagia)
- light hypersensitivity.

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

- restlessness
- erectile dysfunction
- disorientation, difficulties in concentration
- phototoxicity.

Unknown (frequency cannot be estimated from the available data)

- urinary tract infection,
- hypersensitivity
- excitation/agitation, anxiety, seeing or hearing things that are not there (hallucinations), nightmares, paranoia, cognitive disorders in elderly, depression, becoming dependent on Oxybutynin, fits (convulsions), cognitive dysfunction
- narrow angle closure glaucoma, dilation of pupil (mydriasis), ocular hypertension, blurred vision
- Increased heartbeat (tachycardia), irregular heartbeat (arrhythmia
- Indigestion or heartburn (acid reflux), pseudo-obstruction in patients at risk (elderly or patients with constipation and treated with other medicinal products that decrease intestinal motility) urticarial and angioedema,
- allergic reactions such as rash, absence of sweating (hypohidrosis)
- heat stroke

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

For UK - You can also report side effects directly via the Yellow Card Scheme at:  
[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

For Ireland - You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**5. How to store Oxybutynin Tablets**

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

- Do not use this medicine after the expiry date which is stated on the blister or carton. The expiry date refers to the last day of that month.

- Do not store above 30°C. Store in the original package in order to protect from moisture.

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 to protect the environment.

**6. Contents of the pack and other information**

**What Oxybutynin Tablets contains**

The Active substance is Oxybutynin hydrochloride.  
Each tablet contains either 2.5mg or 5mg of the oxybutynin hydrochloride.  
The other ingredients are powdered cellulose, lactose monohydrate, talc and magnesium stearate (E572).

**What Oxybutynin Tablets looks like and contents of the pack**

Oxybutynin 2.5mg Tablets are white to off white, odourless, 5mm round biconvex, uncoated tablets with inscription “BS” on one side and plain on the other side.

Oxybutynin 5mg Tablets are white to off white, odourless, 7.9mm round biconvex, uncoated tablets with inscription “B” and “R” on either side of score line on one side and plain on the other side.  
The 5 mg tablets can be divided into equal halves.

Oxybutynin 2.5 and 5mg Tablets are packed in blisters and further packed in a carton.  
The carton contains 6, 20, 21, 28, 30, 50, 56, 60, 84 and 100 tablets.

Not all pack sizes may be marketed

**Marketing Authorisation Holder**  
Accord Healthcare Limited  
Sage House, 319, Pinner Road, North Harrow  
Middlesex HA1 4 HF  
United Kingdom

**Manufacturer**  
Accord Healthcare Limited  
Sage House, 319 Pinner Road, North Harrow,  
HA1 4HF, Middlesex,  
United Kingdom.

**The medicinal product is authorized in the Member States of the EEA under the following names:**

Name of member state	Name of medicinal product
France	Oxybutynin hydrochloride Accord 5 mg comprimé pelliculé.
Ireland	Oxybutynin hydrochloride 2.5 mg/5 mg tablets
Lithuania	Oxybutynin Accord 5 mg tablets
Latvia	Oxybutynin hydrochloride Accord 5 mg tabletes
Poland	Uralex, 5 mg, tabletki
Sweden	Oxybutynin Accord 2.5 mg/5 mg tabletter
United Kingdom	Oxybutynin hydrochloride 2.5 mg/5 mg tablets

**This leaflet was last revised in 02/2017.**

