

Package leaflet: Information for the user

Oxybutynin Accord 2.5 and 5mg 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 Accord is and what it is used for
2. What you need to know before you take Oxybutynin Accord
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4. Possible side effects
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1. What Oxybutynin Accord is and what it is used for

Oxybutynin Accord 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 Accord can be used to treat:

Adults:

Frequent and severe urinary urgency or Loss of control in passing urine (urge incontinence) caused by damage to the nervous system.

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 Accord

Do not take Oxybutynin Accord and tell your doctor if:

- You are allergic to Oxybutynin 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)” or toxic megacolon (enlarged large intestine).
- You have a blockage that makes it difficult for you to pass water (urine) (e.g. enlarged prostate).
- 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 Accord.

If you suffer from any of the following, you should consult your doctor before starting treatment:

- 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” (such as Parkinson’s disease)
- 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) and/or are concurrently taking medicinal products (such as bisphosphonates) that can cause or worsen oesophagitis.

Oxybutynin must be used with caution in elderly patients due to the risk of side effects that affect cognitive function, the ability to think and memory.

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. It is therefore important to take special care in your oral hygiene while using this medicine. Regular dental check-ups are advisable during long-term treatment.

If you are taking medicines for angina (called nitrates) that have to be dissolved under the tongue, it is also important that you moisten your mouth with your tongue or with a little water before you take one of these tablets.

If oxybutynin is used in hot climate there is a risk for heat prostration due to decreased sweating.

Consult your doctor if you have symptoms such as hallucinations, agitation, confusion and sleep disturbances.

Children

Children below 5 years of age

Oxybutynin Accord 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 Accord

Other medicines and Oxybutynin Accord

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Oxybutynin Accord can affect the way some other medicines work. Also some medicines can affect the way Oxybutynin Accord works.

In particular, tell your doctor if you are taking any one of the following:

- Atropine, compounds related to atropine (used for treatment of cramps) or other anticholinergic medicines (used for treatment in stomach disorders such as irritable bowel syndrome)
- Prochlorperazine, chlorpromazine or other phenothiazines, Clozapine or other antipsychotics (Medicines used to treat psychosis)
- haloperidol, benperidol or other butyrophenones (Medicines used to treat certain mental illness)

- amitriptyline, imipramine, dosulepin or other tricyclic antidepressants (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 or other macrolide antibiotics (used to treat bacterial infections)
- Quinidine (used to treat heart problems)
- Antihistamines (used to treat allergic reactions)
- Metoclopramide or domperidone (medicines affecting (increasing or decreasing) intestinal motility, used to treat nausea)
- Cholinesterase inhibitors (used to treat Alzheimer's disease)

Oxybutynin Accord 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 breast 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. This should be taken into account if a high degree of concentration is required, e.g. when driving or using machines.

Oxybutynin Accord contains lactose

Oxybutynin Accord contains 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.

3. How to take Oxybutynin Tablets

Always take this medicine exactly as your doctor or pharmacist have 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 5 mg 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 the dose according to body weight (0.3 or 0.4 mg/kg/day) to a maximum of:

Age	Dosage
5-9 years	2.5 mg three times daily
9-12 years	5 mg two times daily
Over 12 years	5 mg 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 Accord than you should

If you take more Oxybutynin Accord than you should or if a child has taken the medicine by accident, 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 Accord 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 Accord

Keep taking Oxybutynin Accord until your doctor tells you to stop. Do not stop taking Oxybutynin Accord 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 Accord 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

Contact your doctor immediately if:

you suffer any blurred vision, loss of vision or have any pain in the eye as this might be a sign of glaucoma (increased pressure in the eye).

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)	▪ dizziness, headache, somnolence (feeling drowsy or sleepy) ▪ facial flushing (especially in children) ▪ constipation ▪ nausea ▪ dry mouth ▪ dry skin/decreased sweating
Common (may affect up to 1 in 10 people)	▪ indigestion, diarrhoea, being sick (vomiting) ▪ confusion

	▪ dry eyes ▪ urinary retention ▪ a forceful heartbeat that may be rapid or irregular
Uncommon (may affect up to 1 in 100 people)	▪ loss of appetite (anorexia) ▪ drowsiness ▪ stomach discomfort/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 ▪ excitation
Unknown (frequency cannot be estimated from the available data)	▪ urinary tract infection ▪ hypersensitivity ▪ 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 ▪ dilation of pupil (mydriasis), ocular hypertension, blurred vision, narrow-angle glaucoma ▪ 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) ▪ heart 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. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxybutynin Accord

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 Accord contains

The Active substance is Oxybutynin hydrochloride.

Each tablet contains either 2.5 mg or 5 mg of the oxybutynin hydrochloride.

The other ingredients are powdered cellulose, lactose monohydrate, talc and magnesium stearate (E572).

What Oxybutynin Accord looks like and contents of the pack

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

Oxybutynin Accord 5mg 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

To be completed nationally

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare single member S.A.
64th Km National Road Athens,
Lamia, Schimatari,
32009, Greece

The medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

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

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