

Oxybutynin

Oxybutynin

5 mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start using Oxybutynin.

This leaflet answers some common questions about Oxybutynin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Oxybutynin against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Oxybutynin is used for

Oxybutynin belongs to a group of medicines called anticholinergics and spasmolytics.

Certain types of muscles in your bladder wall (detrusor muscles) increase your urge to urinate when they spasm (contract). Oxybutynin relaxes these muscles and it is therefore used to help control your bladder function.

Oxybutynin is used to treat overactive bladder conditions with the symptoms:

- Urinary incontinence (when you cannot control when you urinate)
- Increased need or urgency to pass urine

Your doctor may have prescribed Oxybutynin for another reason.

Ask your doctor if you have any questions about why Oxybutynin has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Oxybutynin

When you must not use it

Do not use Oxybutynin if:

- If you are allergic to oxybutynin hydrochloride or any of the other ingredients listed at the end of this leaflet
- If you have increased pressure in the eye (glaucoma)
- If you have a blockage that makes it difficult for you to pass urine
- If your gut (stomach or intestine) is blocked
- If your intestinal activity is decreased
- If you suffer from severe inflammatory disease of the large intestine or toxic megacolon (a sudden widening of your lower bowel)
- If you suffer from myasthenia gravis. This is a disease which causes muscle weakness.
- If you are a child under 5 years of age

If you are not sure whether you should start using Oxybutynin, talk to your doctor.

Before you start to use it

Tell your doctor if any of the conditions or illnesses listed below applies to you. You should also talk to your doctor if you have suffered from any of these conditions in the past.

- a disease of the nervous system. For example:
 - multiple sclerosis (a disease affecting the brain and spinal cord)
 - autonomic neuropathy. This is a disease of the autonomic nervous system. The autonomic nervous system is that part of the nervous system that controls your internal organs. These nerves are not under your conscious control and function automatically.
- Parkinson disease and/or if your perception is impaired. Under these conditions, oxybutynin may trigger side effects which affect the nervous system.
- a damaged midriff associated with reflux disease or any other severe diseases of the bowels
- impaired liver and/or kidney function
- hyperthyroidism (an overactive thyroid)
- heart disease or heart failure
- a fast heartbeat (tachycardia) or an irregular heartbeat (arrhythmia)
- high blood pressure (hypertension)
- an enlarged prostate gland
- fever (high body temperature)
- you are 65 years of age or older

If you have not told your doctor about any of the above, tell them before you start using Oxybutynin.

If you treat a child or you are elderly you may be more sensitive to Oxybutynin. Your doctor may give you a reduced dose (see section 'How to use Oxybutynin' for further information on the dosage of Oxybutynin).

Pregnancy and breast-feeding

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.

Do not take Oxybutynin during the first three months of pregnancy. Your doctor may prescribe Oxybutynin from the fourth month of pregnancy if they think that it is clearly necessary.

Do not take Oxybutynin if you are breast-feeding. Oxybutynin may reach your baby through the breast milk.

This medicine contains lactose

Oxybutynin tablets contain milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Oxybutynin.

Some medicines may interfere with Oxybutynin. These include:

- amantadine and other medicines used in Parkinson's disease (e.g. biperiden, levodopa)
- antihistamines (medicines used for allergies e.g. hayfever)
- antipsychotics (e.g. phenothiazines, butyrophenones, clozapine)
- quinidine (for the treatment of heart problems or used as an antimalarial medicine)
- digitalis glycosides (for the treatment of heart problems)
- tricyclic antidepressants (used for depression)
- atropine and related compounds (used for treatment in stomach disorders such as irritable bowel syndrome)
- dipyridamole (used to thin your blood)
- antifungal medicines (e.g. ketoconazole, itraconazole)
- antibiotics called "macrolides" (e.g. erythromycin)
- medicines, that can cause or exacerbate inflammation of the gullet (oesophagitis) such as bisphosphonates (used to treat bone diseases)

These medicines may be affected by Oxybutynin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Oxybutynin may alter the effect of other medicines because it reduces the movement of the guts.

Oxybutynin may also decrease the effect of medicines which affect the bowel movement (e.g. cisapride, metoclopramide, domperidone).

Oxybutynin and alcohol

Oxybutynin may cause drowsiness or blurred vision. Drowsiness may be increased by consumption of alcohol.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Oxybutynin.

How to use Oxybutynin

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. Check with your doctor or pharmacist if you are not sure.

How much to take

Adults

The usual dosage is 5 mg taken 2 to 3 times daily. The maximum recommended dose is 5 mg taken 4 times daily.

Elderly patients

Initially treatment should be 2.5 mg taken 2 times daily and increased as necessary. The maximum recommended dose is 5 mg taken 4 times daily.

Children over 5 years old

The usual dosage is 5 mg taken twice daily. The maximum recommended dose is 5 mg taken 3 times daily.

Oxybutynin is not recommended for children under 5 years.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Up to 5 mg of Oxybutynin may be given as a single dose. Doses above 5 mg should be divided into daily doses.

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Oxybutynin helps control your condition, but does not cure it. Therefore, you must take it every day.

Your doctor will advise you when you can stop taking Oxybutynin completely

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

While you are using Oxybutynin

Things you must do

Your doctor will check your eye-sight and the pressure inside your eyes (intraocular pressure) regularly during therapy. If you have the feeling that your eyes cannot focus properly or your vision is suddenly impaired, please talk to your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Oxybutynin.

Things you must not do

Do not give Oxybutynin to anyone else, even if they have the same condition as you.

You should not take Oxybutynin as a treatment for stress or for incontinence caused by stress (when you cannot control your urge to urinate).

Things to be careful of

Take care if you are working or living in a very hot environment. Oxybutynin causes you to sweat less and this may cause heatstroke.

Long-term use

Oxybutynin also causes you to produce less saliva. Long-term use can lead to problems in your mouth such as:

- caries (rotten teeth)
- diseases of the gums (e.g. periodontal disease)
- general discomfort as a consequence of too less saliva
- thrush

You should be aware that you may get a urinary tract infection during treatment. If you think you are getting an infection you should see your doctor.

Oxybutynin and alcohol

Oxybutynin may cause drowsiness or blurred vision. Drowsiness may be increased by consumption of alcohol.

Driving and using machines

Oxybutynin may influence your reaction times and affect your eye-sight. You may feel drowsy or have blurred vision while you are taking this medicine. This will affect your ability to drive, use machines and perform hazardous work or work without a firm physical support. This may especially be the case at the start of treatment, when increasing the dose, switching medication or drinking alcohol at the same time. Do not drive, use machines or work without a firm support if you notice any side-effects that influence your reaction time or affect your eye-sight.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Oxybutynin.

Do this even if there are no signs of discomfort or poisoning.

Too much oxybutynin has been associated with:

- Excitation of the nervous system (restless or excited)

- Flushing, fever, light headedness or dizziness
- Difficulty in breathing
- Numbness in the hands or feet
- Dehydration
- Irregular heart beat (Cardiac arrhythmia)
- Vomiting
- Difficulty passing Urine (urinary retention)

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Oxybutynin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

The evaluation of the side effects is based on the following frequencies:

Serious side effects:

Stop taking Oxybutynin and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- Swelling of the face, lips or throat, which makes it difficult to swallow or breathe, as well as itching and rashes.

This could be a sign of a severe allergic reaction to Oxybutynin.

Very common (may affect more than 1 user in 10 people):

- dry mouth
- dizziness
- headache
- drowsiness (somnolence)
- difficult, incomplete, or infrequent stool (constipation)
- feeling sick (nausea)
- dry skin

Common (may affect up to 1 to 10 people):

- confusion
- aching tummy, stomach cramps (abdominal discomfort)
- indigestion (dyspepsia)
- a feeling of “spinning” (vertigo)
- blurred vision
- enlarged pupils (mydriasis)
- dry eyes
- skin redness and flushing (sudden reddening of the face)
- problems with urinating
- inability to urinate (urinary retention)
- loose stool (diarrhoea)

- being sick (vomiting)

Uncommon (may affect up to 1 to 100 people):

- loss of appetite (anorexia)
- not knowing where you are (disorientation)
- passivity
- mental or physical tiredness (fatigue)
- light sensitivity
- too rapid heartbeat (tachycardia)
- difficulty swallowing (dysphagia)

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

- heartburn
- concentration and behavioural disorders
- feeling your heartbeat (heart palpitations)
- irregular heartbeat (arrhythmia)

Very rare (may affect up to 1 in 10,000 people):

- fits (convulsions)
- an eye disease causing high pressure inside the eye (glaucoma)
- allergic (hypersensitivity) skin reactions:
 - redness (erythema)
 - rash
 - hives (urticaria)
 - your skin may be more sensitive to sunlight (photosensitivity)
- swelling of the skin, lips or tongue (angio-oedema)
- difficulty getting or keeping an erection (impotence)
- heat stroke

Not known (frequency cannot be estimated from the available data):

- seeing or hearing things that are not there (hallucinations)
- restlessness (agitation)
- fearfulness
- nightmares
- a feeling that others wish to persecute you (paranoia)
- symptoms of depression
- dependence (in patients with history of medicine or substance abuse)
- inflammation of the food pipe due to acid reflux (gastroesophageal reflux disease)
- disorder of gut motility (pseudo-obstruction) in patients at risk (older people or patients with congestion and treated with other medicines that decrease gut motility)
- urinary tract infection
- severe allergic reactions (hypersensitivity)
- difficulty remembering (cognitive disorder) (in older people)
- high pressure in the eye (ocular hypertension)
- sweating less than normal (hypohidrosis)

Reducing your dose may decrease the risk of suffering from the above mentioned side effects.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Oxybutynin

Storage

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

Keep your tablets in the original package.

Keep this medicine in a cool dry place where the temperature stays below 25°C.

Do not use this medicine after the expiry date which is stated on the carton and blister pack.

Disposal

Do not throw away any medicines via wastewater or household waste.

Return to a pharmacy any unused medicine, and any medicine past its expiry date as shown on the dispensing label or on the packaging.

These measures will help protect the environment.

Product description

What it looks like

Oxybutynin 5 mg tablets are white, round tablets, scored on both sides and marked "OBC5" on one side.

Oxybutynin is available in PVC/aluminium blister packs containing 100 tablets.

Ingredients

Active ingredient:

The active ingredient is oxybutynin hydrochloride.

One Oxybutynin 5 mg tablet contains 5 mg of oxybutynin hydrochloride.

Inactive ingredients:

- Cellulose
- Lactose monohydrate
- Magnesium stearate
- Talc

Oxybutynin tablets contain milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sponsor Details

Oxybutynin is supplied in New Zealand by:

Alchemy Health Limited
120 Ngapuhi Road
Remuera
Auckland 1050
NEW ZEALAND

Medical enquires: 0508 ALCHEMY (0508 252436)

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