

1.3.1 Package leaflet - Core

Package leaflet: Information for the user

[Product name] <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 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 [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and further information

1. What [product name] is and what it is used for

[Product name] is a medicine containing an active substance called oxybutynin hydrochloride. Oxybutynin belongs to a group of medicines known as anticholinergics.

Oxybutynin is used in certain types of urinary incontinence, caused by a hyperactive urinary bladder. Oxybutynin decreases muscle spasms of the bladder. It diminishes the frequent urge to urinate, as well as the involuntary loss of urine.

Oxybutynin can be used in children 5 years or 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 [Product name]**Do not take [Product name]**

- if you are **allergic to oxybutynin or any of the other ingredients** of this medicine (listed in section 6).
- if you have a **weakness of your muscles** (Myasthenia Gravis).
- if you have an obstructive **diseases of the intestine** (gut), including obstruction of the bowel.
- if you have **difficulty in passing water** (poor flow) due to a blocked urinary tract or an enlarged prostate.
- if you have **raised pressure in the eye** (glaucoma).
- if you have a disease causing **chronic diarrhoea** (severe ulcerative colitis) or a severe **inflammation of the large intestine** (toxic megacolon).
- if you have a **fast heart beat**.

Warnings and precautions

Check if one of the warnings listed below applies to you or applied to you in the past. Talk to your doctor before taking [Product name]:

- if you are **elderly**.
- if the person taking the medicine is a **child** (use is not recommended under 5 years of age)".
- if you have a **disease of the nervous system** (e.g. autonomic neuropathy).
- if you have a **disease of the oesophagus** (food pipe) or other **stomach or intestinal problems**.
- if you have **liver or kidney problems**.
- if you have an **overactive thyroid gland, a heart disease, heart failure, fast or irregular heart beat, or an enlarged prostate**. The use of oxybutynin may aggravate the symptoms.
- if you have **Parkinson's disease** or problems with memory, language, or another mental function.
- if you have a **raised temperature or fever**.
- if you have a **urinary tract infection**, an appropriate antibacterial therapy should be started before taking oxybutynin.
- if you have been told by your doctor that you have **an intolerance to some sugars**, such as lactose.

Prolonged use of oxybutynin may contribute in the development of caries, bucal disease, oral candidiasis (a yeast infection) and discomfort due to decrease or inhibition of the salivary flow.

Other medicines and [Product name]

Other medicines may be affected by oxybutynin. They, in turn, may affect how well oxybutynin works. Oxybutynin can interact with:

- medicines to treat mental illness (phenothiazines, butyrophenones)
- medicines to treat to treat Parkinson's disease (amantadine, L-dopa).
- a certain type of antidepressants (tricyclic antidepressants).
- medicines used to treat heart problems (digitalis, quinidine, procainamide)
- other anti-cholinergic medicines (e.g. atropine).
- medicines to treat digestive problems and that act on the muscles of your digestive system (e.g. metoclopramide).
- certain antifungal medicines (e.g. ketoconazole) or antibiotics (e.g. erythromycin)

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

[Product name] with food and drink

Oxybutynin may be taken with water on an empty stomach.

Oxybutynin may also be taken during meals or with some milk if gastric irritation occurs.

Pregnancy and breast-feeding

Oxybutynin should **not be used during pregnancy**, unless it is clearly indicated by your doctor that you can use oxybutynin. Insufficient data are available to evaluate the safety of oxybutynin during pregnancy.

You should not breast-feed while taking oxybutynin. When oxybutynin is used during breast-feeding, a small amount is excreted in mother's milk.

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.

Driving and using machines

Oxybutynin can sometimes cause blurred vision, drowsiness or dizziness. You should not plan to drive or operate machinery until you are sure that you are not affected by this. If you are affected, do not drive or operate machinery during treatment with oxybutynin.

[Product name] contains lactose

[Product name] contains the 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 medicinal product.

3 How to take [Product name]

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

The tablet should be taken orally with water on an empty stomach. The tablets may also be taken during meals or with some milk if gastric irritation occurs.

Use in adults

For adults the **usual starting dose** is 2.5 mg three times daily. If necessary, your doctor may increase this dose up to 5 mg three to four times a day (maximum dose is 20 mg per day).

Use in older people

For **older** people the usual starting dose is 2.5 mg twice a day. Your dose needs to be carefully adjusted to your needs by your doctor.

Use in children and adolescents

For **children over 5 years of age** the usual starting dose is 2.5 mg twice a day. Based on a recommended dose of 0.3 - 0.4 mg/kg body weight per day, your doctor may increase the dose according to the following table:

Age	Dosage
5-9 years	2.5 mg 3 times daily
9-12 years	5 mg 2 times daily
12 years and older	5 mg 3 times daily

This medicine is not recommended for **children under 5 years of age**.

If you take more [Product name] than you should

If you have taken more oxybutynin than you should, **contact your doctor or pharmacist immediately**.

If you forget to take [Product name]

If you forget to take the dose at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten tablet.

If you stop taking [Product name]

Do not stop taking your oxybutynin, even if you are feeling well, unless your doctor tells you to. Your doctor will advise you on how long you should continue to take your tablets.

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.

Side effects can be:

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

- dry mouth

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

- dizziness, drowsiness
- pupil dilatation (mydriasis)
- blurred vision
- constipation
- dyspepsia (indigestion)
- nausea
- abdominal pain
- facial flushing
- discomfort urinating

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

- confusion, disorientation
- apathy
- pain or fullness in your eye(s) (narrow-angle glaucoma)
- dry eyes
- diarrhoea
- vomiting
- anorexia
- dry skin
- urinary retention
- headache

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

- behavioural and concentration disturbances
- tachycardia (faster heart beat) or arrhythmia (irregular heart beat)
- impotence

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

- convulsions
- allergic skin reactions
- heat stroke

Not Known side effects (frequency cannot be estimated from the available data)

- Agitation
- Anxiety
- Hallucination
- Nightmares
- Paranoia
- Elderly patients may feel confused (cognitive disorders)
- Symptoms of depression
- Dependence (in patients with history of drug or substance abuse)
- Heartburn (reflux oesophagitis)
- Abdominal discomfort in patients at risk (elderly or patients with constipation and treated with other medical products that decrease intestinal motility).

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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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 packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and 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 protect the environment.

6 Contents of the pack and other information

What [Product name] contains

- The active substance is oxybutynin hydrochloride
Each tablet contains 5 mg oxybutynin hydrochloride.
- The other ingredients are cellactose (cellulose and lactose), cellulose powder, talc and magnesium stearate.

What [Product name] looks like and contents of the pack

[Product name] is a white round tablet, scored with a division mark on both sides and debossed with OBC 5 on one side.

[Product name] is available in boxes containing 20, 21, 30, 50, 60, 84, 100, 300 or 600 tablets in strips.

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

<This medicinal product is authorised in the Member States of the EEA under the following names:>

[To be completed nationally]

This leaflet was last revised in {MM/YYYY}.

<[To be completed nationally]>