Oxybutynin Hydrochloride Tablets 5mg

Read all of this leaflet carefully before you start taking this medicine.

• 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is called Oxybutynin Hydrochloride Tablets 5 mg. They will be referred to as Oxybutynin Tablets throughout this leaflet for ease.

In this leaflet:
1. What Oxybutynin Tablets are and what they are used for
2. Before you take Oxybutynin Tablets
3. How to take Oxybutynin Tablets
4. Possible side effects
5. How to store Oxybutynin Tablets
6. Further information

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

The active substance in Oxybutynin Tablets is oxybutynin hydrochloride. This is one of a group of medicines called anticholinergics or antispasmodics. It increases the volume of the bladder by relaxing the muscle of the bladder wall, and helps to control the release of urine.

It is used to treat the following conditions:

Adults:
• Loss of control in passing water (urinary incontinence), urgency and frequency in patients unable to control their bladder
• Neurogenic bladder disorders (lack of bladder control caused by problems with the nervous system or spinal cord)

Children over 5 years:
• 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. Before you take Oxybutynin Tablets

Do not take Oxybutynin Tablets if you:
• are allergic (hypersensitive) to oxybutynin hydrochloride or any of the ingredients of Oxybutynin Tablets (see section 6, Further Information, for a list of ingredients)
• have diseases or obstructions of the intestine (gut), including bowel obstruction or no bowel movement
• have a blocked urinary tract (causing a poor flow of urine)
• have a condition called myasthenia gravis (a muscle weakening disease)
• have glaucoma (high pressure and pain in the eyes)
• • have **megacolon** (greatly enlarged colon) or **severe colitis** (inflammation of the colon)

*Take special care and talk to your doctor or pharmacist before taking Oxybutynin Tablets if any of the following apply to you:*
  * an **overactive thyroid gland** (a gland in your neck)
  * heart disease, **heart failure**, fast or irregular heartbeat, high blood pressure
  * an **enlarged prostate gland** (in men)
  * **hiatus hernia**
  * **reflux oesophagitis** (a condition affecting the food pipe).

The tablets should be used with caution in
  * the **elderly**
  * the person taking the medicine is a **child** (use is not recommended under 5 years of age)
  * patients with diseases of the **nervous system, liver or kidneys**
  * patients with **movement disorders of the gut**.

Avoid exposure to extreme heat, as oxybutynin may make it harder for your body to cool down when it gets very hot. You may suffer from fever and heat stroke due to decreased sweating.

Since oxybutynin can cause increased pressure in the eye (narrow-angle glaucoma). Contact your doctor immediately if you are aware of a sudden loss of visual sharpness, or you experience pain in your eye(s).

Oxybutynin may reduce saliva production in your mouth, which could result in tooth decay or an infection in your mouth.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, interaction with any of the following may alter the effect of the medicine:
  * antipsychotics (e.g. phenothiazines, butyrophenolnes, clozapine) or tranquilizers (e.g. chlorpromazine, thioridazine and fluphenazine)
  * amantadine (used in Parkinson’s disease or to treat and prevent some viral infections)
  * haloperidol (used to treat certain mental illnesses)
  * biperiden, levodopa (used in Parkinson’s disease)
  * digitalis (a heart medicine)
  * Quinidine (a medicine prescribed for the treatment of abnormal heart rhythms)
  * tricyclic antidepressants
  * sedatives (e.g. diazepam and oxazepam)
  * other anticholinergic medicines (similar to oxybutynin)
  * antihistamines (used to treat a number of allergic health conditions)
    atropine (used to treat a number of problems including spasms in the gut) and related medicines like atropinic antispasmodics and dipyridamole.
  * inhibitors of Cytochrome P 450 enzymes (a class of enzymes found in the liver, which are involved in the metabolism of many medications
• medicines which enhance movement in the small intestine (prokinetic therapies)

• medicines which inhibit a family of enzymes called cholinesterases

• alcohol may increase the drowsiness caused by anticholinergic agents such as oxybutynin

Taking Oxybutynin Tablets with food and drink
Oxybutynin Tablets should be swallowed with plenty of water, with or without food. If you take alcohol while taking these tablets, you may become very drowsy.

Pregnancy and breast-feeding
You should not take Oxybutynin Tablets if you are pregnant or breast-feeding. If you are planning to become pregnant or suspect you might be pregnant, talk to your doctor before taking your tablets. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Oxybutynin Tablets can sometimes cause blurred vision, drowsiness or dizziness. If you get any of these symptoms, do not drive or use any tools or machines until they go away. If you are unsure, speak to your doctor or pharmacist.

Important information about some of the ingredients of Oxybutynin Tablets
This medicine contains a type of sugar called lactose monohydrate. If you have been told by your doctor that you are intolerant to some sugars and have to avoid them, contact your doctor before taking this medicine.

3. How to take Oxybutynin Tablets
Always take Oxybutynin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is 5 mg swallowed two or three times a day. Occasionally, 5 mg four times a day is required.

Elderly: The usual dose is 5 mg swallowed two or three times a day, however, as the drug can remain in the body for longer in elderly patients, 5 mg twice a day is usually sufficient.

Children over 5 years: The usual dose is 5 mg swallowed twice a day. Your doctor might decide to increase the dose to three times a day if needed.

Nocturnal enuresis (night time bedwetting): The usual dose is 5 mg swallowed two or three times a day. The last dose should be given just before bedtime.

Children under 5 years: Not recommended.

Sometimes your doctor may reduce your dose, especially when you have been taking your tablets for some time.
If you take more Oxybutynin Tablets than you should
If you accidentally take more than your prescribed dose, contact a doctor or your nearest hospital casualty department immediately. Take this leaflet and the pack with you.

If you forget to take Oxybutynin Tablets
If you forget to take a dose, take it as soon as you remember and then continue with the next dose as usual. Do not take an extra tablet to make up for missed doses.

If you stop taking Oxybutynin Tablets
Keep taking your medicine until your doctor tells you to stop. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Oxybutynin Tablets can cause side effects, although not everybody gets them. Stop taking Oxybutanin Tablets and see a doctor or go to a hospital straight away if:
• you have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Tell your doctor if you suffer from diarrhoea during your treatment with Oxybutynin Tablets (especially if you have had an ileostomy or a colostomy), as this could be an early sign of intestinal obstruction.

Side effects reported by patients taking Oxybutynin Tablets include:

Very common (affects more than 1 user in 10):
• dry skin
• dry mouth
• constipation
• feeling sick (nausea)
• headache
• drowsiness, general feeling of weakness and tiredness

Common (affects 1 to 10 users in 100):
• flushing of the face
• difficulty passing water
• dizziness
• dry eyes
• confusion
• vomiting
• diarrhoea

Uncommon (affects 1 to 10 users in 1 000):
• photosensitivity
• difficulty sleeping
• disorientation
• discomfort in the belly (abdomen)
• decreased appetite
• anorexia
• restlessness

Not known (cannot be estimated from the available data)
• urinary tract infection
• skin rash
• fast, irregular or pounding heartbeats
• decrease in sweating
• heatstroke
• anxiety
• agitation
• paranoia
• nightmares
• hallucinations (seeing and hearing things that are not there)
• blurred vision,
• pressure on the eye (glaucoma)
• pupil dilation (mydriasis)
• cognitive disorders
• convulsions
• condition where acid from the stomach leaks out of the stomach and up into the oesophagus or gullet (gastroesophageal reflux disease)
• abdominal pain and bloating which may be accompanied by feeling or being sick, difficulty with swallowing, diarrhoea or constipation, depending on the part of the gut affected. (pseudo obstruction)
• depression
• becoming dependent on oxybutynin.

**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](http://www.mhra.gov.uk/yellowcard)

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

**5. How to store Oxybutynin Tablets**
Keep out of the reach and sight of children.
Do not use Oxybutynin Tablets after the expiry date which is stated on the carton and blister strip. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions. Do not use Oxybutynin Tablets if the tablets show visible signs of deterioration.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Further information**
**What Oxybutynin Tablets contain**
The active substance is oxybutynin hydrochloride. Each 5 mg tablet contains 5 mg oxybutynin hydrochloride. The other ingredients are cellulose, lactose, magnesium
stearate and purified talc (E553). **What Oxybutynin Tablets look like and contents of the pack**

Oxybutynin Hydrochloride Tablets are white uncoated tablets. They are packed in blister strips and supplied in cartons of 21, 28, 30, 56, 60, 84, 100 and 120 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Actavis, Barnstaple, EX32 8NS, UK.

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