PACKAGE LEAFLET: INFORMATION FOR THE USER

Oxybutynin hydrochloride 5mg prolonged-release tablets
Oxybutynin hydrochloride 10mg prolonged-release tablets
Oxybutynin

The name of your medicine is Oxybutynin hydrochloride Prolonged release tablets which will be referred to as "Oxybutynin" throughout this leaflet.

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

1. WHAT OXYBUTYNIN IS AND WHAT IT IS USED FOR

This medicine contains oxybutynin hydrochloride. This belongs to a group of medicines called 'anticholinergics' or 'antispasmodics'. Oxybutynin works by relaxing your bladder muscles. It also stops bladder contractions and delays the desire to pass urine (water).

Your tablets are made in a 'prolonged release' form. The tablets are coated with a 'special membrane', which slowly releases the medicine. This membrane may pass through your body unchanged. This does not affect the way the medicine works.

Oxybutynin can be used:

- To help adults control when and how often they pass urine.
- 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.

If your symptoms do not improve after 7 days talk to your doctor.

You must talk to a doctor if at any time your symptoms worsen.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OXYBUTYNIN

Do not take this medicine

- if you are allergic to oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have raised pressure in your eye (glaucoma)
- if you have a muscle weakness problem called 'myasthenia gravis'
- if you have a feeling of incomplete emptying of the bladder (urinary retention)
- if you have a problem with your gut (stomach or intestine) called 'toxic megacolon', 'paralytic ileus' or 'intestinal atony'. These are when your gut is blocked, perforated or not working properly
- if you have a severe form of condition known as 'ulcerative colitis'. This is a disease that causes frequent diarrhoea
- if you have heart or kidney failure and need to pass urine more often than usual, especially at night
- if you have a blood problem called 'porphyria'

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine:

- if you are elderly and frail (weak or in poor health) as you may be more sensitive to Oxybutynin
- if you have a problem with your gut (stomach or intestine)
- if you have hiatal hernia, reflux disease (GORD) or heart burn
- if you are taking medicines to treat osteoporosis (drugs known as bisphosphonates)
- if you have kidney or liver problems
- if you have a problem called 'bladder outflow obstruction' which makes it difficult to pass urine
- if you have a urinary tract infection
- if you have an overactive thyroid
- if you have heart problems
- if you have high blood pressure
- if you have prostate problems
- if you have something called 'dementia' (memory loss and confusion) and are being treated for it with a certain type of medicine, such as donepezil, rivastigmine, galantamine or tacrine
- if you have Parkinson's disease

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking this medicine.

This medicine may reduce the amount of saliva resulting in tooth decay, gum disease, or fungal infection of the mouth (oral thrush).

Hot weather or fever

Care must be taken when using this medicine in hot weather or in people with a fever. This is because this medicine reduces the amount a person sweats. This can lead to heat exhaustion and heat stroke.

Children and adolescents

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

Other medicines and Oxybutynin

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

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- For mental problems such as phenothiazines or butyrophenones and clozapine
- For depression called 'tricyclic antidepressants' (such as amitriptyline or desipramine)
- For Parkinson's disease such as amantadine or levodopa
- For allergy called 'antihistamines' (such as chlorphenamine or diphenhydramine)
- For heart problems such as quinidine or digitalis
- For treating or preventing muscle spasms (antispasmodics such as diazepam)
- Used to thin your blood called dipyridamole
- Other anticholinergic medicines such as atropine for glaucoma or hyoscine for nausea
- For dementia such as donepezil, rivastigmine, galantamine or tacrine
- Placed under the tongue to treat angina (sublingual nitrates)
- For fungal infections such as ketoconazole, itraconazole and fluconazole
- Antibiotics called 'macrolides' (such as erythromycin)
- Domperidone and metoclopramide – used to stop you feeling sick (nausea) or being sick (vomiting)
- Medicines used to help empty the stomach and move foods through the gut (such as domperidone)

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking this medicine.

Oxybutynin with alcohol

Oxybutynin may make you feel sleepy, and this may be increased by consumption of alcohol. For this reason, it's advisable not to drink alcohol while taking this medicine.

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.

Driving and using machines

There have been reports of dizziness and blurred vision with the use of Oxybutynin. You should therefore be careful when driving, using machinery or performing other tasks that need full attention.

Oxybutynin contains lactose

This medicine contains lactose (1.68mg), a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Information on Sodium content

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE OXYBUTYNIN

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

- Oxybutynin should be taken once daily
- Take your medicine at the same time each day
- Swallow the tablet whole with a glass of water
- Do not chew, break or crush the tablet
- You can take your medicine with food or in between meals.

How much to take

Your doctor will decide what dose of medicine is best for you.

Use in adults

- The recommended starting dose is normally one 5mg tablet each day
- After at least one week, your doctor may increase your dose to 10mg each day
- Your doctor may increase this to a maximum of 20mg each day
- Your doctor will leave a gap of at least one week between changing the dose.

Use in children (over 5 years)

- The recommended starting dose is normally one 5mg tablet each day
- Your child's doctor may increase the dose to a maximum of 15mg each day.

If you take more of this medicine than you should

If you think that you have taken too many tablets, tell a doctor or go to the nearest hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You may experience symptoms starting as restlessness and excitement, and worsening to circulation changes such as flushing or drop in blood pressure, difficulty breathing, being unable to move your body and losing consciousness.

If you forget to take this medicine

- Do not take a double dose to make up for a forgotten dose
- If you forget a dose, do not worry. Just skip that dose and take your next dose at the regular time.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Oxybutynin and see a doctor or go to a hospital straight away if:

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

- You have a severe allergic reaction. The signs may include: a rash, hives (also known as nettle rash or urticaria), difficulty swallowing or breathing, swelling of your lips, face, throat or tongue
- You have central nervous system (CNS) effects (changes in thinking or emotions) such as anxiety, nervousness, seeing or hearing things that are not actually there, and trouble thinking clearly or making decisions. Watch for these signs, particularly in the first few months after you start taking your medicine or after an increase in dose.

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

- You have a sudden decrease in vision, eye pain and/or high pressure in the eye, which may cause blindness (glaucoma)
- You experience seizures (fits).

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

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

- Dry mouth

This is more common at doses of more than 10mg once a day and may lead to tooth decay, gum disease or fungal infection. This may also prevent medicines you put under your tongue dissolving properly (such as angina medicines).

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

- Abnormal awareness of your heartbeat (palpitations)
- Blurred eyesight, dry eyes
- Constipation, diarrhoea, nausea, indigestion, stomach pain, change in the way things taste, feeling bloated (flatulence) or heartburn
- Feeling tired
- Dry skin or itching
- Feeling dizzy or sleepy, having a headache, problems sleeping
- Pain passing urine, delay when starting to pass urine, feeling of incomplete emptying of your bladder, urinary tract infection
- Dry nose, dry or sore throat, cough.

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

- Seeing or hearing things that are not there (hallucinations)
- Feeling agitated or confused, difficulty remembering
- Allergic reaction
- Difficulty swallowing
- Thirst
- Loss of appetite, vomiting, frequent bowel movements
- Nasal congestion, impairment of the voice, such as hoarseness
- Irregular heartbeat, racing heart
- High blood pressure
- Chest discomfort
- Retaining water
- Flushing
- Falling
- Rash.

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

- Psychological problems
- Difficulty getting or keeping an erection
- Anxiety
- Becoming dependent on Oxybutynin
- Nightmares
- Depression
- Paranoia
- Difficulty thinking, remembering information, or solving problems
- Dilated pupils
- Lack of sweating
- Heat stroke
- 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).

Additional side effects in children

Constipation is a very common side effect in children. The following are common side effects in children: Loss of appetite, diarrhoea, headache, problems sleeping, rash or itching, flushing.

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 the Yellow Card Scheme (website: **www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store)**. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OXYBUTYNIN

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 carton and bottle label after 'EXP'. The expiry date refers to the last day of that month.

Store your medicine in the original package. Keep the container tightly closed in order to protect from moisture.

5mg only: Store below 25°C.

10mg only: This medicinal product does not require any temperature storage conditions.

Do not remove or swallow the sachet of granules in the bottle. This contains a desiccant, which keeps the tablets dry.

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 Oxybutynin contains

The active substance is oxybutynin hydrochloride. Each prolonged-release tablet contains either 5mg or 10mg of oxybutynin hydrochloride.

The other ingredients are:

5mg:

Core: Polyethylene oxide, hypromellose, sodium chloride, butylated hydroxytoluene, colloidal silicon dioxide, magnesium stearate, iron oxide yellow (E172), iron oxide black (E172).

Film Coating: Cellulose acetate, polyethylene glycol 3350, hypromellose, titanium dioxide, lactose monohydrate, triacetin, iron oxide yellow (E172), iron oxide black (E172).

Printing Ink: Shellac (E904), propylene glycol, iron oxide black, purified water.

10mg:

Core: Polyethylene oxide, hypromellose, sodium chloride, butylated hydroxytoluene, colloidal silicon dioxide, magnesium stearate, iron oxide red (E172), iron oxide black (E172).

Film Coating: Cellulose acetate, polyethylene glycol 3350, hypromellose, titanium dioxide, lactose monohydrate, triacetin, iron oxide red (E172).

Printing Ink: Shellac (E904), propylene glycol, iron oxide black, purified water.

What Oxybutynin looks like and contents of the pack

Oxybutynin 5mg: Pale yellow coloured, round, biconvex tablets with orifice and "P5" imprinted with black ink.

Oxybutynin 10mg: Pink coloured, round, biconvex tablets with orifice and "P10" imprinted with black ink.

Your medicine is available in bottles containing 14, 28, 30, 56, 60, 84, 90, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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GU32 3QG
United Kingdom

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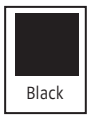
ASPIRE® PHARMA

Aspire Pharma Limited	
Product name	Oxybutynin Hydrochloride
Size:	x1
PL/PA no:	35533.0142-143
Type:	Leaflet
Artwork dimensions (mm):	420 x 280mm
Reason for request:	Storage condition change
Version no:	3.1
Date of revision:	23.9.25
Font(s):	Myriad pro 8pt
A/W software:	Indesign CC



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