Package leaflet: Information for the user
Oxybutynin hydrochloride 5mg/5ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine because it contains impotant 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.

The name of your medicine is Oxybutynin hydrochloride 5mg/5ml Oral Solution but it will be referred to as Oxybutynin throughout this leaflet.

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

Oxybutynin 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 can be used in adults and children 5 years or older to treat:

- ▶ loss of control in passing water (urinary incontinence)
- ▶ increased need or urgency to pass water (urine)
- ▶ night time bedwetting, when other treatments have not worked

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Oxybutynin

Do not take Oxybutynin if:

- ▶ you are allergic to oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- ▶ you have a rare muscle illness called 'Myasthenia gravis'
- ▶ you have increased pressure in the eye (glaucoma)
- ▶ your gut (stomach or intestine) is blocked, perforated or not working properly (intestinal atomy or intestinal occlusion, toxic megacolon)
- ▶ you have a severe form of a condition known as 'ulcerative colitis'
- ▶ you have a blockage that makes it difficult for you to pass water (urine).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxybutynin if:

- ▶ you are 65 years of age or older
- ▶ you have certain heart conditions (deficiency congestive heart failure, coronary heart disease)
- ▶ the person taking the medicine is a child (use is not recommended under 5 years of age)
- ▶ you have brain problems (such as hallucinations, agitation, confusion, drowsiness)
- ▶ you have kidney or liver problems
- ▶ you have stomach or bowel problems (such as bowel obstruction, bowel laziness, inflammation of bowel)
- ▶ you have neurological disorders (such as Parkinson's disease)
- ▶ you have an illness affecting the nerves called 'autonomic neuropathy'
- ▶ you have eye problem (such as glaucoma)
- ▶ you have an overactive thyroid gland ('Hyperthyroidism')
- ▶ you have dental caries or a fungal infection in the mouth
- ▶ 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 indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm)
- ▶ you have a raised body temperature or fever
- ▶ you will be taking this medicine in a hot climate
- ▶ you have long-term illness
- ▶ you have a urinary tract infection
- ▶ you have acid reflux in your mouth, sometimes responsible for digestive burns (gastrosoesophageal reflux disease)
- ▶ you are taking medicines (such as bisphosphonates) at the same time that may cause or exacerbate inflammation of the oesophagus.
- ▶ you urinate unintentionally after exertion

During treatment

- If you are taking oxybutynin long-term, this may reduce the amount of saliva which may cause caries, damage to your gums (parodontolysis), and/or infection in your mouth caused by certain microscopic fungi (candidiasis).
- If you have hyperthyroidism (excessive thyroid gland activity), heart disease, increased blood pressure (hypertension),
- cognitive impairment (such as memory impairment and comprehension), or increased prostate volume, oxybutynin may worsen these diseases.
- If nervous system effects (e.g. hallucinations, agitation, confusion, sleepiness) occur, your doctor should be advised
- Oxybutynin may cause an increase in the pressure of the liquid in the eye and may affect the view (glaucoma). You should contact your doctor immediately if you notice a sudden loss of vision or if you experience pain in your eye.
- Oxybutynin may cause oxybutynin dependence in patients with a history of substance abuse

Elderly:

People over 65 years of age may be more sensitive to the effects of the medicine due to the risk of cognitive impairment. Your doctor will need to take this into account if you are in this situation.

Children and adolescents

Do not give this medicine to children under the age of 5 years.

Children 5 years of age and older:
Children are more likely to have side effects. Therefore, oxybutynin should be used with caution in this age group.
If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Oxybutynin.

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, including herbal medicines. This is because Oxybutynin can affect the way some medicines work. Also some medicines can affect the way Oxybutynin work.

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

- ▶ Other anticholinergic or antimuscarinic medicines - such as some medicines for irritable bowel syndrome, asthma or incontinence, motion sickness or movement disorders associated with Parkinson's disease
- ▶ Some medicines used to treat dementia (e.g. donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors))
- ▶ Some medicines for stomach and gut problems (e.g. domperidone, metoclopramide, bethanechol)
- ▶ CYP3A inhibitors (e.g. ketoconazole, itraconazole or fluconazole used to treat fungal infections or erythromycin, or other macrolide antibiotics used to treat bacterial infections)
- ▶ Medicines used to make you feel sleepy (sedatives) or if you are feeling sick (nausea) or have vertigo - such as prochlorperazine or chlorpromazine
- ▶ Medicines used to treat certain mental illnesses - such as clozapine, phenothiazines, haloperidol or benperidol (butyrophenones)
- ▶ Medicines for depression - such as amitriptyline, imipramine or dosulepin ('tricyclic antidepressants') and lithium
- ▶ Amantadine, biperiden, levodopa - used in Parkinson's disease or to treat and prevent some viral infections
- ▶ Aminopenicillins, tetracyclines, sulfamethoxazole, cotrimoxazole - drugs used for inhibition of bacterial infections
- ▶ Digoxin, quinidine, disopyr amide, procainamide and lidocaine - used to treat heart problems
- ▶ Dipyridamole - used to treat blood problems
- ▶ Antihistamines - used to treat allergies
- ▶ Paracetamol - used to treat pain
- ▶ Phenylbutazone - used to treat inflammation
- ▶ Atropine and related compounds - drugs used for spasms of the digestive tract

Oxybutynin with food, beverages and alcohol

Alcohol may increase drowsiness caused by oxybutynin.

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if:

- ▶ You are pregnant, think you may be pregnant or are planning to have a baby. You should not take this medicine if you are pregnant without your doctor's advice.
- ▶ You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk. Breast feeding while using Oxybutynin is therefore not recommended.

TURN OVER

Driving and using machines
You may feel drowsy or have blurred vision while you are taking this medicine. If this happens, do not drive or use any tools or machines.

Oxybutynin contains:

Sorbitol (E420): This medicine contains 896mg sorbitol in each 5ml dose which is equivalent to 179.2mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
Methyl parahydroxybenzoate (E218): may cause allergic reactions (possibly delayed).
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.
Propylene glycol (E1520): This medicine contains 15.5mg propylene glycol in each 5ml dose which is equivalent to 3.1mg/ml.

3. How to take Oxybutynin

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

The recommended doses are given below. These may be changed by your doctor:
Adults
- The starting dose is 2.5mg (2.5ml) three times a day
- The usual dose is 5mg (5ml) two or three times a day
- Your doctor may decide to increase to the maximum dose of 5mg (5ml) four times a day

Elderly
- The usual dose is 2.5mg (2.5ml) twice a day
- Your doctor may decide to increase this dose by weight to 0.3 or 0.4 mg/kg/day

Children (over 5 years)
- The usual dose is 2.5mg (2.5ml) twice a day
- Your doctor may decide to increase this to 5mg (5ml) two or three times a day
- If you are giving it to a child to prevent bedwetting, give the last dose just before bedtime

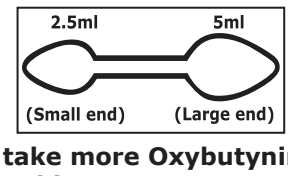
In some cases, your doctor may increase the dose to a maximum of:

Age	Standard dosage
5-9 years	2.5 mg (2.5 ml) 3 times daily
9-12 years	5 mg (5 ml) twice daily
12 years and older	5 mg (5 ml) 3 times daily

Your doctor may review you after 4 to 6 weeks to assess the effectiveness of the treatment.

Method of administration
- For oral use only
- Use the 2.5-5ml double-ended spoon supplied in the pack to measure the required dose (see figure below).
- Swallow the solution.
- Wash the spoon with clean water after taking every dose.

2.5 - 5ml double-ended Spoon



If you take more Oxybutynin than you should
Contact your nearest hospital casualty department or tell your doctor immediately. Take the medicine pack with you. This is so the doctor knows what you have taken.
Taking too much Oxybutynin can be very dangerous. You may become very restless or excited, flushed or get dizzy or light-headed. You may have redness or your blood pressure may fall. 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
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
Keep taking Oxybutynin until your doctor tells you to stop. Do not stop taking Oxybutynin 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 and contact your doctor immediately if you develop the following symptoms:
- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You feel reduced sweating, leading to overheating in hot environments

Other side effects:
Very common: may affect more than 1 in 10 people
- Dry mouth, constipation, nausea
- Dizziness, headache, drowsiness
- Dry skin
- Blurred vision

Common: may affect up to 1 in 10 people
- Diarrhoea, vomiting
- Confusional state
- Dry eyes
- Inability or difficulty in passing water (urine)
- Flushing
- Strong heartbeat which may be rapid or irregular.

Uncommon: may affect up to 1 in 100 people
- Stomach pain, loss of appetite (anorexia), decrease appetite, difficulty in swallowing (dysphagia)

Not known: cannot be estimated from the available data
- A bladder infection (Urinary tract infection)
- Indigestion or heartburn (acidreflux)
- Fits (convulsions)
- Agitation
- Seeing or hearing things that are not there (hallucinations), delirium
- Cognitive impairment (especially in the elderly)
- Nightmares
- A forceful heartbeat that may be rapid or irregular
- Enlargement of the pupil of the eye, increased pressure in the eyes (glaucoma), dry eyes
- Rash or skin that is more sensitive to the sun
- Anxiety
- Mental Health disorders
- Symptoms of depression
- Dependence on oxybutynin (in patients with a history of addiction to substances)
- Paranoia
- Shaking
- Allergic reaction
- Muscle weakness, muscle pain or cramps
- Nosebleed
- Abnormal reduction in sweating (hypohidrosis) which can lead to heat stroke
- Intestinal motility disorders (obstruction) in some patients

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.
- Do not store above 25°C.
- Discard 30 days after first opening. Store in the original packaging after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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 5ml oral solution contains 5mg oxybutynin hydrochloride.

The other ingredients are citric acid monohydrate (E330), sodium citrate (E331), liquid sorbitol (non-crystallising) (E420), glycerol (E422), methyl parahydroxybenzoate (E218), raspberry flavour (containing propylene glycol (E1520)) and purified water.

What Oxybutynin looks like and contents of the pack
Oxybutynin is a clear, colourless oral solution with raspberry odour and supplied in amber glass bottles with tamper evident, child resistant plastic cap and with a 2.5-5ml double ended spoon for measuring the dose.

Oxybutynin hydrochloride 5mg/5ml oral solution is supplied in bottles containing 100ml and 150ml solution.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
SyriMed,
Unit 4, Bradfield Road,
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POM

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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