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Package leaflet: Information for the patient

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

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, 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.
- The full name of this medicine is Oxybutynin hydrochloride XL 5mg, 10mg prolonged release tablets, but within the leaflet it will be referred to as Oxybutynin hydrochloride XL.

What is in this leaflet

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

1. What Oxybutynin hydrochloride XL is and what it is used for

Oxybutynin hydrochloride XL contains a medicine called oxybutynin hydrochloride. This belongs to a group of medicines called 'anticholinergics' or 'antispasmodics'.

Oxybutynin hydrochloride XL 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 release the medicine. This membrane may pass through your body unchanged. This does not affect the way the medicine works.
Oxybutynin hydrochloride XL 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 hydrochloride XL

Do not take Oxybutynin hydrochloride XL
- 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 blockage that makes emptying of the bladder difficult (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 a blood problem called 'porphyria'.

Do not use Oxybutynin hydrochloride XL if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before taking Oxybutynin hydrochloride XL.

Warnings and precautions
Talk to your doctor or pharmacist before taking Oxybutynin hydrochloride XL if you:
- are elderly and frail (weak or in poor health), because of the risk of cognitive impairment and being at greater risk of adverse reactions
- have a problem with your gut (stomach or intestine) or a disease called ulcerative colitis
- have hiatal hernia, reflux disease (GERD) or heart burn
- have kidney or liver problems
- have a problem called 'bladder outflow obstruction' which makes it difficult to pass urine
- have an overactive thyroid (hyperthyroidism)
- have an irregular heartbeat (palpitation, arrythmias) and/or rapid heartbeat
- have heart disease or high blood pressure
- have prostate problems
- 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
- have an illness affecting the nerves called 'autonomic neuropathy', such as Parkinson's disease.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before taking Oxybutynin hydrochloride XL.

Oxybutynin hydrochloride XL 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 Oxybutynin hydrochloride XL in hot weather or in people with a fever. This is because Oxybutynin hydrochloride XL reduces the amount a person sweats. This can lead to heat exhaustion and heat stroke.

Children
Oxybutynin hydrochloride XL is not recommended in children under 5 years of age.
Other medicines and Oxybutynin hydrochloride XL
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 medicines. This is because Oxybutynin hydrochloride XL can affect the way some medicines work. Also, some other medicines can affect the way Oxybutynin hydrochloride XL works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- For mental problems such as phenothiazines or butyrophenones, haloperidol or clozapine
- For depression called 'tricyclic antidepressants' (such as amitriptyline, imipramine or dosulepin)
- For Parkinson's disease such as amantadine or levodopa
- For allergy called 'antihistamines' (such as chlorphenamine)
- For heart problems
- For treating or preventing muscle spasms (antispasmodics)
- Other anticholinergic medicines such as atropine for glaucoma or hyoscine for nausea
- For dementia (such as cholinesterase inhibitors)
- Placed under the tongue to treat angina (sublingual nitrates)
- For fungal infections such as ketoconazole or itraconazole
- Macrolide antibiotics to treat bacterial infections
- To treat nausea and vomiting (such as prochlorperazine or chlorpromazine)
- Medicines used to help empty the stomach and move foods through the gut.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Oxybutynin hydrochloride XL.

Oxybutynin hydrochloride XL with alcohol
Oxybutynin hydrochloride XL 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.

While breast-feeding, small amounts may pass into mothers' milk. Breast-feeding while using this medicine is therefore not recommended.

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

Oxybutynin hydrochloride XL contains 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.

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

3. How to take Oxybutynin hydrochloride XL

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 hydrochloride XL 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 inbetween 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 5 mg tablet each day
- After at least one week, your doctor may increase your dose to 10 mg each day
- Your doctor may increase this to a maximum of 20 mg 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 5 mg tablet each day
- Your child's doctor may increase the dose to a maximum of 15 mg each day.

If you take more Oxybutynin hydrochloride XL 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 Oxybutynin hydrochloride XL
- 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 hydrochloride XL and contact your doctor or go to the nearest hospital emergency department immediately if you think you have any of the following serious side effects:
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 (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 (may affect more than 1 in 10 people):
- Feeling dizzy or sleepy, having a headache
- Blurred vision
- Constipation, nausea
- Dry skin
- Dry mouth. This is more common at doses of more than 10 mg 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 (may affect up to 1 in 10 people):
- A forceful heartbeat that may be rapid or irregular
- Racing heartbeat
- Dry eyes
- Diarrhoea, vomiting, indigestion, stomach pain, change in the way things taste, feeling bloated (flatulence) or heartburn
- Flushing (especially in children)
- Feeling tired
- Itching
- Feeling confused, problems sleeping
- Pain passing urine, delay when starting to pass urine, incomplete emptying of your bladder, retaining water, urinary tract infection
- Dry nose, dry or sore throat, cough.

Uncommon (may affect up to 1 in 100 people):
- Seeing or hearing things that are not there (hallucinations)
- Feeling agitated, difficulty remembering
- Allergic reaction
- Difficulty swallowing
- Thirst
- Loss of appetite, frequent bowel movements
- Nasal congestion, impairment of the voice, such as hoarseness
- Irregular heartbeat
- High blood pressure
- Chest discomfort
- 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
- Feeling drowsy or disorientated
- Nosebleed
- Dilated pupils
- Lack of sweating
- Skin that is more sensitive to the sun (photosensitivity)
- Heat stroke
- Muscle weakness, pain or cramps
- 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, 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 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 hydrochloride XL

- 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 “Expiry”. The expiry date refers to the last day of that month.
- Store your medicine in the original package. This medicinal product does not require any special storage conditions. Keep the container tightly closed in order to protect from moisture.
- Do not remove or swallow the canister of granules. This contains 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 hydrochloride XL contains

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

The other ingredients are:
Oxybutynin hydrochloride XL 5mg prolonged release tablets:
Core:
Lactose Monohydrate, Microcrystalline Cellulose, Hydroxypropylmethyl cellulose (K100 Premium LV CR), Hydroxypropylmethyl cellulose (K100 M), Iron Oxide Yellow, Purified Talc, Colloidal Anhydrous Silicon Dioxide, Magnesium Stearate.

Film coat:
Opadry OY-29020 Clear contains; HPMC 2910/Hypromellose, Macrogol/PEG.

Enteric coating:
Acryl-EZE 93O520016 Yellow contains; Methacrylic acid and Ethylacrylate Copolymer, Talc, Titanium Dioxide, Triethyl Citrate, Colloidal anhydrous Silica, Sodium bicarbonate, Iron oxide yellow, Sodium Lauryl Sulfate, Iron oxide red.

Printing Ink:
Opacode Black S-1-17823 contains; Shellac Glaze~45% (20%Esterified) in Ethanol, IsopropyL alcohol, Ferrosoferric oxide (NF)/Black iron oxide, N-butyl alcohol, Propylene glycol, Ammonium hydroxide 28%.

Oxybutynin hydrochloride XL 10mg prolonged release tablets:
Core:
Lactose Monohydrate, Microcrystalline Cellulose, Hydroxypropylmethyl cellulose (K100 Premium LV CR), Hydroxypropylmethyl cellulose (K100 M), Iron Oxide Yellow, Iron Oxide Red, Purified Talc, Colloidal Anhydrous Silicon Dioxide, Magnesium Stearate.

Film coat:
Opadry OY-29020 Clear contains; HPMC 2910/Hypromellose, Macrogol/PEG.

Enteric coat:
Acryl – EZE 93O540011 Pink contains; Methacrylic acid and Ethylacrylate Copolymer, Talc, Titanium Dioxide, Triethyl Citrate, Colloidal anhydrous Silica, Sodium bicarbonate, Sodium Lauryl Sulfate, Iron oxide red, Iron oxide yellow.

Printing Ink:
Opacode Black S-1-17823 contains; Shellac Glaze~45% (20%Esterified) in Ethanol, IsopropyL alcohol, Ferrosoferric oxide (NF)/Black iron oxide, N-butyl alcohol, Propylene glycol, Ammonium hydroxide 28%.

What Oxybutynin hydrochloride XL looks like and contents of the pack
Oxybutynin hydrochloride XL 5mg prolonged release tablets
Pale yellow colored, round shaped, biconvex coated tablets imprinted with "EM1" on one side and plain on other side.

Oxybutynin hydrochloride XL 10mg prolonged release tablets
Pink colored, round shaped, biconvex coated tablets imprinted with "EM2" on one side and plain on other side.

This medicine is available in bottles containing 28, 30, 56 or 84 tablets. Not all pack sizes may be marketed.

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