

Package leaflet: Information for the user

LYRINEL® XL 10 mg prolonged release 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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Lyrinel XL is and what it is used for

The name of your medicine is Lyrinel XL prolonged release tablets. It is called Lyrinel XL in this leaflet. Lyrinel XL contains a medicine called oxybutynin hydrochloride. This belongs to a group of medicines called 'anticholinergics' or 'antispasmodics'.

Lyrinel 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.

Lyrinel 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 Lyrinel XL

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Lyrinel XL

- if you are elderly and frail (weak or in poor health) as you may be more sensitive to Lyrinel XL
- if you have a problem with your gut (stomach or intestine)
- if you have hiatal hernia, reflux disease (GERD) 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 Lyrinel XL.

Lyrinel 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 Lyrinel XL in hot weather or in people with a fever.

This is because Lyrinel XL reduces the amount a person sweats. This can lead to heat exhaustion and heat stroke.

Children

Lyrinel XL is not recommended in children under 5 years of age.

Other medicines and Lyrinel 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 therapies. This is because Lyrinel XL can affect the way some other medicines work. Also, some other medicines can affect the way Lyrinel XL 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.

Lyrinel XL with alcohol

Lyrinel 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.

Driving and using machines

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

Lyrinel XL contains lactose

Lyrinel XL tablets contain lactose (0.03 mg), 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.

Lyrinel XL contains sodium chloride

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

3. How to take Lyrinel 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.

- Lyrinel 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 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 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 Lyrinel 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 Lyrinel 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 Lyrinel XL 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 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 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 Lyrinel XL
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via: HPRC Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Lyrinel 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 EXP. The expiry date refers to the last day of that month.

Store your medicine in the original package. Do not store above 25 °C. Keep the container tightly closed in order to protect from moisture.

Do not remove or swallow the sachet of granules in the bottle. 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 Lyrinel XL contains

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

The other ingredients (excipients) are:

Butylhydroxytoluene (E321), cellulose acetate 398-10, hypromellose 5 cp, polyethylene glycol 3350, magnesium stearate, polyethylene oxide 200K, polyethylene oxide 2000K, sodium chloride, black iron oxide (E172), ferric oxide red (E172) and lactose anhydrous.

Film coat: ferric oxide red (E172), hypromellose 3 cp and 6 cp, polyethylene glycol 400, polysorbate 80 and titanium dioxide (E171).

Printing Ink: black iron oxide (E172), hypromellose 6 cp and propylene glycol.

What Lyrinel XL looks like and contents of the pack

Round, pink coloured tablet printed "10 XL" with black ink.

Your medicine is available in bottles containing 30 tablets.

Manufacturer:

Janssen-Cilag SpA, Via C. Janssen-Cilag Ltd, Borgo S. Michele, 04100 Latina, Italy

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation number: PPA 465/486/1

Lyrinel is a registered trademark of Janssen-Cilag Ltd.

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

Name of the member state	Name of the medicinal product
Greece	LYRINEL
Ireland	LYRINEL XL
Italy	LYRINEL
United Kingdom	LYRINEL XL

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