

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lyrinel[®] XL 5 mg prolonged release tablets

Oxybutynin hydrochloride

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, nurse 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Lyrinel is and what it is used for
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1. WHAT LYRINEL IS AND WHAT IT IS USED FOR

What Lyrinel is

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

How Lyrinel works

Lyrinel 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.

What Lyrinel is used for

Lyrinel 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

2. BEFORE YOU TAKE LYRINEL

Do not take Lyrinel if:

- You are allergic (hypersensitive) to oxybutynin hydrochloride or any of the other ingredients of Lyrinel (listed in Section 6 below)
- You have raised pressure in your eye (glaucoma)
- You have a muscle weakness problem called 'myasthenia gravis'
- You have a feeling of incomplete emptying of the bladder (urinary retention)
- 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
- You have a severe form of condition known as 'ulcerative colitis'. This is a disease that causes frequent diarrhoea
- You have heart or kidney failure and need to pass urine more often than usual, especially at night
- You have a blood problem called 'porphyria'.

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

Take special care with Lyrinel

Check with your doctor, nurse or pharmacist before taking Lyrinel if:

- You are elderly and frail (weak or in poor health) as you may be more sensitive to Lyrinel
- You have a problem with your gut (stomach or intestine)
- You have kidney or liver problems
- You have a problem called 'bladder outflow obstruction' which makes it difficult to pass urine
- You have a urinary tract infection
- You have an overactive thyroid
- You have heart problems
- You have high blood pressure
- You have prostate problems
- 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.
- The person taking the medicine is a child (use is not recommended under 5 years of age).

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

Hot weather or fever

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

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, and herbal therapies. This is because Lyrinel can affect the way some other medicines work. Also, some other medicines can affect the way Lyrinel 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
- 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).

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

Pregnancy and breast-feeding

Talk to your doctor, nurse or pharmacist before taking Lyrinel if you are pregnant, might become pregnant or think you may be pregnant.

Do not breast-feed if you are taking Lyrinel. This is because small amounts may pass into your milk.

Ask your doctor, nurse or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

You may feel drowsy or have blurred vision while taking Lyrinel. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Lyrinel

Lyrinel tablets contain lactose, 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.

3. HOW TO TAKE LYRINEL

Always take Lyrinel exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

How to take Lyrinel

- Lyrinel 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.

Adults

- The 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.

Children (over 5 years)

- The 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 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

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lyrinel can cause some side effects, although not everybody gets them.

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

- You have an 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.
- You have a sudden change in the clearness of your eyesight.

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

Very common (affects 1 in 10 people or more)

- 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 (affects less than 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 (affects less than 1 in 100 people)

- Seeing or hearing things that are not there (hallucinations)
- Psychological problems, feeling agitated or confused, difficulty remembering
- Allergic reaction including hives or swelling of the face, lips, tongue or throat
- Difficulty in swallowing
- Thirst
- Loss of appetite, vomiting, frequent bowel movements
- High pressure and pain in the eyes (glaucoma), unable to tolerate light
- Nasal congestion, impairment of the voice, such as hoarseness
- Irregular heartbeat, racing heart
- High blood pressure
- Chest discomfort
- Retaining water
- Convulsions
- Flushing
- Falling
- rash

Other side effects:

- Difficulty breathing due to a serious allergic reaction
- Psychological problems

- Difficulty getting or keeping an erection

Common 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist. Seek medical attention immediately if you have an allergic reaction and difficulty breathing.

5. HOW TO STORE LYRINEL

Keep out of the reach and sight of children.

Do not use Lyrinel 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.

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 Lyrinel contains

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

The other ingredients are:

butylhydroxytoluene (E321), cellulose acetate, hypromellose, macrogol, magnesium stearate, polyethylene oxide, sodium chloride, black iron oxide (E172), ferric oxide yellow (E172) and lactose anhydrous.

Film coat: ferric oxide yellow (E172), hypromellose, macrogol, polysorbate 80 and titanium dioxide (E171)

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

What Lyrinel looks like and contents of the pack

Lyrinel XL 5 mg prolonged release tablet: round yellow coloured tablet, approximately 7.5 mm in diameter, printed with "5 XL" on one side in black ink.

Your medicine is available in bottles containing 30 tablets.

Manufacturer

Janssen-Cilag SpA, Latina, Italy or Janssen Pharmaceutica NV, Beerse, Belgium

Product procured from within the EU & repackaged by the Parallel Product Authorisation holder:

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

Parallel Product Authorisation Number: PPA 465/295/1

Lyrinel is a registered trademark of JOHNSON & JOHNSON

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
Portugal	LYRINEL
United Kingdom	LYRINEL XL

This leaflet was last approved by PCO Manufacturing in July 2014