PACKAGE LEAFLET: INFORMATION FOR THE USER

Blerone XL 4mg prolonged-release capsules

Tolterodine tartrate

Read all of this leaflet carefully before you start using 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.
- 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.

In this leaflet:

1. What Blerone XL is and what it is used for
2. What you need to know before you take Blerone XL
3. How to take Blerone XL
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1. What Blerone XL is and what it is used for

The name of your medicine is Blerone XL 4mg prolonged-release capsules (called Blerone XL throughout this leaflet). The active substance in Blerone XL is tolterodine. Tolterodine belongs to a class of medicinal products called antimuscarinics.

Blerone XL is used for the treatment of the symptoms of overactive bladder syndrome. If you have overactive bladder syndrome, you may find that:
- you are unable to control urination
- you need to rush to the toilet with no advance warning and/or go to the toilet frequently

2. What you need to know before you take Blerone XL

Do not take Blerone XL if you:
- are allergic to the active substance or any of the other ingredients in this medicine (listed in section 6).
- are unable to pass urine from the bladder (urinary retention).
- have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eyesight that is not being adequately treated).
- suffer from myasthenia gravis (excessive weakness of the muscles).
- suffer from severe ulcerative colitis (ulceration and inflammation of the colon).
- suffer from a toxic megacolon (acute dilatation of the colon).

Warnings and precautions
Talk to your doctor or pharmacist before taking Blerone XL if you:
- have difficulties in passing urine and/or a poor stream of urine.
- have a gastro-intestinal disease that affects the passage and/or digestion of food.
- suffer from kidney problems (renal insufficiency).
- have a liver condition.
- suffer from neurological disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system).
- have a hiatus hernia (herniation of an abdominal organ).
- ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility).
- have a heart condition such as:
  - an abnormal heart tracing (ECG)
  - a slow heart rate (bradycardia)
  - relevant pre-existing cardiac diseases such as: cardiomyopathy (weak heart muscle), myocardial ischaemia (reduced blood flow to the heart), arrhythmia (irregular heartbeat) and heart failure
- have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Other medicines and Blerone XL
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tolterodine, the active substance of Blerone XL, may interact with other medicinal products.

It is not recommended to use tolterodine in combination with:
- some antibiotics (containing e.g. erythromycin, clarithromycin).
- medicinal products used for the treatment of fungal infections (containing e.g. ketoconazole, itraconazole).
- medicinal products used for the treatment of HIV.

Blerone XL should be used with caution when taken in combination with:
- medicines that affect the passage of food (containing e.g. metoclopramide and cisapride)
- medicines for the treatment of irregular heartbeat (containing e.g. amiodarone, sotalol, quinidine, procainamide)
- other medicines with a similar mode of action to Blerone XL (antimuscarinic properties) or medicines with an opposite mode of action to Blerone XL (cholinergic properties). The reduction in gastric motility caused by antimuscarinics may affect the absorption of other drugs. Ask your doctor if you are unsure.

Blerone XL with food and drink
Blerone XL can be taken before, after or during a meal.

Pregnancy and breast-feeding
If you are pregnant, breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You should not use Blerone XL when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Breast-feeding
It is not known if tolterodine, the active substance of Blerone XL, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of Blerone XL.

Driving and using machines
Blerone XL may make you feel dizzy, tired or affect your sight. If you experience any of these effects then you should not drive your car or operate heavy machinery.

Blerone 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.

3. How to take Blerone XL

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

Adults:
The recommended dose is one 4mg prolonged-release hard capsule daily.

Patients with liver or kidney problems:
In patients with liver or kidney problems your doctor may reduce your dose to 2mg Blerone XL daily.

Children:
Blerone XL is not recommended for children.

The prolonged-release hard capsules are for oral use and should be swallowed whole.
Do not chew the capsules.

If you have taken more Blerone XL than you should
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately. Symptoms in case of overdose include hallucinations, excitation, a heartbeat faster than usual, dilation of the pupil and inability to urinate or breathe normally.

If you forget to take Blerone XL
If you forget to take a dose at the usual time, take it as soon as you remember unless it is almost time for your next dose. In that case, omit the forgotten dose and follow the normal dose schedule.
Do not take a double dose to make up for a forgotten one.

If you stop taking Blerone XL
Your doctor will tell you how long your treatment with Blerone XL will last. Do not stop treatment early because you do not see an immediate effect. Your bladder will need some time to adapt. Finish the course of prolonged-release capsules prescribed by your doctor. If you have not noticed any effect by then, talk to your doctor.

The benefit of the treatment should be re-evaluated after 2 or 3 months. Always consult your doctor if you are thinking of stopping the treatment.

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.

You should see your doctor immediately or go to the casualty department if you experience symptoms of:
- severe allergic reaction or angioedema (frequency is not known, cannot be estimated from the available data), such as:
  - swollen face, tongue or pharynx.
  - difficulty in swallowing or breathing.
  - hives, rash, itching.
- heart failure (occurs uncommonly, may affect up to 1 in 100 people), such as:
  - chest pain, difficulty breathing or getting tired easily (even at rest), difficulty breathing at night, swelling of the legs.

The following side effects have been observed during treatment with tolterodine with the following frequencies.

Very common (may affect more than 1 in 10 people):
- Dry mouth

Common (may affect up to 1 in 10 people):
- Sinusitis
- Sleepiness
- Dry eyes
- Difficulty with digestion (dyspepsia)
- Abdominal pain
- Painful or difficult urination
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Dizziness
- Headache
- Blurred vision
- Constipation
- Excessive amounts of air or gases in the stomach or the intestine
- Diarrhoea
- Tiredness

Uncommon (may affect up to 1 in 100 people):
- Allergic reactions
- Nervousness
- Palpitations
- Inability to empty the bladder
- Vertigo
- Heart failure
- Irregular heartbeat
- Chest pain
- Sensation of pins and needles in the fingers and toes
- Memory impairment

Not known (frequency cannot be estimated from the available data):
- Confusion, hallucinations and disorientation
- Heart burn
- Vomiting
- Increase heart rate
- Flushed skin
- Dry skin

There have also been reports of worsening symptoms of dementia in patients being treated for dementia.

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 at: 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 Blerone 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 label/carton. The expiry date refers to the last day of that month.

Do not store above 30°C

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 Blerone XL contains
The active substance in Blerone XL 4mg prolonged-release capsules, is 4 mg of tolterodine tartrate, equivalent to 2.74mg of tolterodine.

The other ingredients are:
Lactose monohydrate, cellulose microcrystalline, poly(vinyl acetate), povidone, silica, sodium laurylsulfate, sodium docusate, magnesium stearate, hydroxypropylmethylcellulose
Capsule composition: indigo carmine (E132), titanium dioxide (E171), gelatine.
Inner tablet coating: ethylcellulose, triethyl citrate, methacrylic acid - ethyl acrylate copolymer, 1,2-propylene glycol

What Blerone XL looks like and contents of the pack
Blerone XL is a hard prolonged-release capsule designed for once daily dosing.
Blerone XL 4mg prolonged-release capsules (19.4x6.9 mm) are light blue opaque-light blue opaque.

Blister packs containing: 7, 14, 28, 49, 84, 98 prolonged-release hard capsules

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer
Marketing authorisation holder:
Zentiva Pharma UK Limited, 12 New Fetter Lane,
London EC4A 1JP, United Kingdom

Manufacturer:
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