

Lotprosin XL 8mg, 16mg and 24mg Prolonged-release Capsules, hard Galantamine

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 Lotprosin XL 8mg, 16mg and 24mg Prolonged-release Capsules, hard but within the leaflet it will be referred to as Lotprosin XL capsules.

What is in this leaflet:

- 1 What Lotprosin XL capsules are and what they are used for**
- 2 What you need to know before you take Lotprosin XL capsules**
- 3 How to take Lotprosin XL capsules**
- 4 Possible side effects**
- 5 How to store Lotprosin XL capsules**
- 6 Contents of the pack and other information**

1 What Lotprosin XL capsules are and what they are used for

Lotprosin XL capsules contains the active substance 'galantamine', an antimentia medicine. It is used in adults to treat the symptoms of mild to moderately severe Alzheimer's disease, a type of dementia that alters brain function.

Alzheimer's disease causes increasing memory loss, confusion and behavioural changes, which make it increasingly difficult to carry out normal daily activities. These effects are thought to be caused by a lack of 'acetylcholine', a substance responsible for sending messages between brain cells. Lotprosin XL capsules increases the amount of acetylcholine in the brain and treats the signs of the disease.

The capsules are made in a 'prolonged-release' form. This means that they release the medicine slowly.

2 What you need to know before you take Lotprosin XL capsules

Do not take Lotprosin XL capsules

- If you are **allergic** to galantamine or to any of the other ingredients of this medicine (listed in section 6).
- If you have **severe liver** or **severe kidney** disease.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Lotprosin XL capsules

This medicine is only used in Alzheimer's disease and is not recommended for other types of memory loss or confusion.

Serious side effects

Lotprosin XL capsules can cause serious skin reactions, heart problems and fits (seizures). You must be aware of these side effects while you are taking Lotprosin XL capsules. See 'Look out for serious side effects' in section 4.

Before you take Lotprosin XL capsules, your doctor needs to know if you have, or have had, any of the following :

- **liver** or **kidney** problems
- a **heart** condition (such as chest discomfort that is often brought on by physical activity, a heart attack, heart failure, slow or uneven heart beat)
- changes in '**electrolyte**' levels (naturally occurring chemicals in the blood, such as potassium)
- a **peptic** (stomach) **ulcer**
- **blockage** of the **stomach** or **intestines**
- a disorder of the **nervous system** (such as epilepsy or Parkinson's disease)
- a **respiratory disease** or infection that affects breathing (such as asthma, obstructive pulmonary disease or pneumonia)
- **problems passing urine**.

Your doctor will decide if Lotprosin XL capsules is suitable for you, or if the dose needs to be changed.

Also tell your doctor if you recently had an operation on the stomach, intestines or bladder. Your doctor may decide that Lotprosin XL capsules is not suitable for you.

Lotprosin XL capsules **can cause weight loss**. Your doctor will check your weight regularly while you are taking Lotprosin XL capsules.

Children and adolescents

Lotprosin XL capsules is not recommended for children and adolescents.

Other medicines and Lotprosin XL capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Lotprosin XL capsules should not be used with medicines that work in a similar way. These include:

- donepezil or rivastigmine (for Alzheimer's disease)
- ambenonium, neostigmine or pyridostigmine (for severe muscle weakness)
- pilocarpine (when taken by mouth for dry mouth or dry eyes).

Some medicines can make side effects more likely in people taking Lotprosin XL. These include:

- paroxetine or fluoxetine (antidepressants)
- quinidine (for uneven heart beat)
- ketoconazole (an antifungal)
- erythromycin (an antibiotic)
- ritonavir (for human immunodeficiency virus or 'HIV').
- non-steroidal anti-inflammatory painkillers (such as ibuprofen) which can increase the risk of ulcers
- medicines taken for heart conditions or high blood pressure (such as digoxin, amiodarone, atropine, beta-blockers, or calcium channel blocking agents). If you take medicines for an uneven heart-beat, your doctor may check your heart using an electrocardiogram (ECG).

Your doctor may give you a lower dose of Lotprosin XL capsules if you are taking some of these medicines.

Lotprosin XL capsules may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking Lotprosin XL capsules, well in advance.

If you need an operation which requires a general anaesthetic, you should inform the doctor that you are taking Lotprosin XL capsules.

If you have any questions, talk to your doctor, pharmacist or nurse for advice.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not breastfeed while you are taking Lotprosin XL capsules.

Driving and using machines

Lotprosin XL capsules may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If Lotprosin XL capsules affects you, do not drive or use any tools or machinery.

3 How to take Lotprosin XL capsules

Always take Lotprosin XL capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you are currently taking Galantamine immediate release tablets or oral solution and have been told by your doctor to switch to Lotprosin XL capsules, read the instructions at the end of this section carefully.

How much to take

You will start treatment with Lotprosin XL capsules at a low dose. The usual starting dose is 8 mg, taken once a day. Your doctor may gradually increase your dose, every 4 weeks or more, until you reach a dose that is suitable for you. The maximum dose is 24 mg, taken once a day.

Your doctor will explain what dose to start with and when the dose should be increased. If you are not sure what to do, or find the effect of Lotprosin XL capsules is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will need to see you regularly to check that this medicine is working and to discuss how you are feeling.

If you have liver or kidney problems, your doctor may give you a reduced dose of Lotprosin XL capsules, or may decide this medicine is not suitable for you.

Switching from taking Galantamine tablets or oral solution to Lotprosin XL capsules

If you are currently taking Galantamine tablets or oral solution, your doctor may decide you should switch to Lotprosin XL capsules. If this applies to you:

- Take your last dose of Galantamine tablets or oral solution in the evening
- The next morning, take your first dose of Lotprosin XL capsules.

DO NOT take more than one capsule in a day. While you are taking once-daily Lotprosin XL capsules, DO NOT take Galantamine tablets or oral solution.

How to take

Lotprosin XL capsules must be swallowed whole and NOT chewed or crushed. Take your dose of Lotprosin XL capsules once a day in the morning, with water or other liquids. Try to take Lotprosin XL capsules with food.

Drink plenty of liquids while you are taking Lotprosin XL capsules, to keep yourself hydrated.

If you take more Lotprosin XL capsules than you should

If you take too much Lotprosin XL capsules, contact a doctor or hospital straight away. Take along any remaining capsules and the packaging with you. The signs of overdose may include: severe nausea and vomiting, weak muscles, slow heartbeat, fits (seizures) and loss of consciousness.

If you forget to take Lotprosin XL capsules

If you forget to take one dose, miss out the forgotten dose completely and take the next dose at the normal time.

Do not take a double dose to make up for a forgotten dose.

If you forget to take more than one dose, contact your doctor.

If you stop taking Lotprosin XL capsules

Check with your doctor before you stop taking Lotprosin XL capsules. It is important to continue taking this medicine to treat your condition.

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 your medicine and see a doctor immediately or go to your nearest emergency department if you notice any of the following;

Skin reactions, including:

- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).
- Rash that may blister, with spots that look like small targets. These skin reactions are rare in people taking Lotprosin XL capsules (may affect up to 1 in 1,000 people).
- **Heart problems** including changes in heart beat (such as a slow beat, extra beats) or palpitations (heart beat feels fast or uneven). Heart problems may show as an abnormal tracing on an 'electrocardiogram' (ECG), and can be common in people taking Lotprosin XL capsules (may affect up to 1 in 10 people)
- **Fits (seizures)**. These are uncommon in people taking Lotprosin XL capsules (may affect up to 1 in 100 people).

You must stop taking Lotprosin XL capsules and get help immediately if you notice any of the side effects above.

Other side effects:

Very common side effects (may affect more than 1 in 10 people):

- Nausea and vomiting. These side effects are more likely to happen in the first few weeks of treatment or when the dose is increased. They tend to disappear gradually as the body gets used to the medicine and generally only last for a few days. If you have these effects, your doctor may recommend that you drink more liquids and, may prescribe a medicine to stop you being sick.

Common side effects (may affect up to 1 in 10 people):

- Decreased appetite; weight loss
- Seeing, feeling, or hearing things that are not there (hallucinations)
- Depression
- Feeling dizzy or fainting
- Muscle tremors or spasms
- Headache
- Feeling very tired, weak or generally unwell
- Feeling very sleepy with low energy
- High blood pressure
- Stomach pain or discomfort
- Diarrhoea
- Indigestion
- Falls
- Wounds

Uncommon side effects (may affect up to 1 in 100 people):

- Allergic reaction
- Not enough water in the body (dehydration)
- Tingling or numb feeling of the skin (pins and needles)
- Change in sense of taste
- Daytime sleepiness
- Blurred vision
- Ringing in the ears that does not go away (tinnitus)
- Low blood pressure
- Flushing
- Feeling the need to vomit (retch)
- Excessive sweating
- Weak muscles
- Increased level of liver enzymes in the blood

Rare side effects (may affect up to 1 in 1,000 people):

- Inflamed liver (hepatitis).

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 internet at www.mhra.gov.uk/yellowcard

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

5 How to store Lotprosin XL capsules

Keep out of the sight and reach of children.

Do not use Lotprosin XL capsules after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Contents of the pack and other information

What Lotprosin XL capsules contain:

The active substance is galantamine.

- Lotprosin XL 8mg Prolonged-release Capsules contain 8mg galantamine (as hydrobromide)
- Lotprosin XL 16mg Prolonged-release Capsules contain 16mg galantamine (as hydrobromide)
- Lotprosin XL 24mg Prolonged-release Capsules contain 24mg galantamine (as hydrobromide)

The other ingredients are:

Capsule contents: Cellulose microcrystalline, Hypromellose, Ethylcellulose and Magnesium stearate. Capsule shell: Gelatin and Titanium dioxide (E 171).
• The 16mg capsule also contains red iron oxide (E 172).
• The 24mg capsule also contains Indigo carmine (E 132), Erythrosin (E 127), Red Iron Oxide (E 172) and Yellow iron oxide (E 172).

What Lotprosin XL capsules look like and contents of the pack

Lotprosin XL Prolonged-release Capsules, hard are available in three strengths, each of which can be recognised by its colour:

- 8mg: Opaque white size 2 hard gelatine capsules containing one round biconvex tablet
- 16mg: Opaque flesh size 2 hard gelatine capsules containing two round biconvex tablets
- 24mg: Opaque orange size 2 hard gelatine capsules containing three round biconvex tablets.

Pack size: 28

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