

Package leaflet: Information for the patient

Acumor XL 8 mg prolonged release capsules
Acumor XL 16 mg prolonged release capsules
Acumor XL 24 mg prolonged release capsules
(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 are a carer and will be giving Acumor XL to the person you look after, it is also important that you read this leaflet on their behalf.
- 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.

What is in this leaflet:

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

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

Acumor XL contains galantamine, which is an antimentia medicine used to treat the symptoms of mild to moderately severe dementia of the Alzheimer type, a disease that alters brain function.

The symptoms of Alzheimer's disease include increasing memory loss, confusion and behavioural changes. As a result, it becomes more and more difficult to carry out normal daily activities. These symptoms are believed to be due to a lack of acetylcholine, a substance responsible for sending messages between brain cells. Galantamine increases the amount of acetylcholine in the brain and so could improve the symptoms 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 Acumor XL

Do not take Acumor XL:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Acumor XL.

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

Before you take this medicine, your doctor needs to know if you have, or have had, any of the following:

- other liver or kidney problems
- a heart condition (such as chest discomfort that is often brought on by physical activity (angina), heart attack, heart failure, slow or uneven heart beat, prolonged QTc interval)
- reduced blood flow to the brain, a stroke or a mini-stroke (also known as a transient ischaemic attack or 'TIA')
- changes in "electrolyte" levels (if your blood potassium levels are decreased or increased)
- a peptic (stomach) ulcer
- blockage of the stomach or intestines (which may cause abdominal pain or severe constipation)
- 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 Acumor XL 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 this medicine is not suitable for you.

During treatment

If you need an operation, which requires a general anaesthetic, tell your doctor, or the hospital staff, that you are taking Acumor XL.

This medicine can cause weight loss. Your doctor will check your weight regularly while you are taking this medicine.

Serious side effects

This medicine can cause serious skin reactions, heart problems, and fits (seizures). You need to be aware of these side effects whilst you are taking this medicine. See section 4 for more information.

Children and adolescents

Acumor XL is not recommended for children and adolescents.

Other medicines and Acumor XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

Galantamine 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 muscular weakness)
- pilocarpine (for dry mouth or dry eyes) if taken by mouth

Some medicines can affect the way galantamine works, or galantamine itself can reduce the effectiveness of other medicines taken at the same time. Your doctor may prescribe a smaller dose of Acumor XL if you are taking any of those medicines. These include:

- paroxetine or fluoxetine (antidepressants)
- quinidine (used for heart rhythm problems)
- ketoconazole (antifungal)
- erythromycin (antibiotic)
- ritonavir (antiviral – HIV protease inhibitor)

Some medicines make side effects more likely in people taking galantamine. These include:

- non-steroidal anti-inflammatory painkillers (e.g. 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 irregular heartbeat, your doctor may consider an electrocardiogram (ECG).
- medicines affecting the QTc interval.

If you have any questions, speak to your doctor or pharmacist 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 breast-feed while you are taking Acumor XL.

Driving and using machines

Galantamine may cause dizziness or drowsiness, especially during the first few weeks of treatment. If you experience these symptoms, do not drive or use any tools or machinery.

Acumor XL contains allura red (E129) and sodium

Allura red (E129, an azo colouring agent) may cause allergic reactions.

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

3. How to take Acumor 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.

If you are currently taking galantamine tablets or oral solution and have been told by your doctor to switch to Acumor XL read the instructions at the end of this section carefully.

How to take Acumor XL

Acumor XL should be swallowed whole, NOT chewed or crushed. Acumor XL should be taken in the morning, with water or other liquids, and preferably with food.

Acumor XL is available in 3 strengths: 8 mg, 16 mg and 24 mg. Acumor XL is started at a low dose. Your doctor may then tell you to slowly increase the dose (strength) of Acumor XL that you take to find the most suitable dose for you.

1. The recommended starting dose is 8 mg capsule taken once daily. After 4 weeks of treatment, the dose may be increased.
2. You would then take the 16 mg capsule once daily. After another 4 weeks of treatment at the earliest, your doctor may decide to increase the dose again.
3. You would then take the 24 mg capsule once daily.

Your doctor will explain what dose to start with and when the dose should be increased. If you feel that the effect of Acumor XL 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 for you and to discuss how you are feeling. Your doctor will also check your weight regularly while you are taking galantamine.

If you have liver or kidney problems

- If you have mild liver or kidney problems, treatment is started with the 8 mg capsule once daily in the morning.
- If you have moderate liver problems, treatment is started with the 8 mg capsule once every other day in the morning. After one week, begin taking the 8 mg capsule once daily in the morning. Do not take more than 16 mg once daily.
- If you have severe liver and/or kidney problems, do not take Acumor XL.

If you take more Acumor XL than you should

If you take too much Acumor XL, contact a doctor or hospital straight away. Take along any remaining capsules and the packaging with you. Signs or symptoms of overdose may include: severe nausea, vomiting, muscle weakness, slow heartbeat, seizures and loss of consciousness.

If you forget to take Acumor XL

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, you should talk to your doctor.

If you stop taking Acumor XL

You should talk to your doctor before you stop taking Acumor XL. 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.

How do I switch from taking galantamine tablets or oral solution to Acumor XL?

If you are currently taking galantamine tablets or oral solution, your doctor may decide to switch you to Acumor XL.

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Look out for serious side effects

Stop taking this medicine and see a doctor immediately if you experience:

- **Heart problems** including slow heart beat (common: may affect up to 1 in 10 people). You may also notice other changes in heart beat such as extra beats or palpitations (heart beat feels fast or uneven), which may show as an abnormal tracking on an electrocardiogram (ECG) (uncommon: may affect up to 1 in 100 people).
- **Fits (seizures)** (uncommon: may affect up to 1 in 100 people).
- **Allergic reactions.** You may notice a rash, itching or hives, swelling of the face, lips, tongue, shortness of breath (uncommon: may affect up to 1 in 100 people).
- **Inflammation of the liver (hepatitis).** You may notice stomach pain, yellowing of the skin or eyes, pale stools or dark urine (rare: may affect up to 1 in 1,000 people).
- **Skin reactions** (rare: may affect up to 1 in 1,000 people), 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 generalised exanthematous pustulosis).
 - Rash that may blister, with spots that look like small targets.

Other side effects:

Very common: may affect more than 1 in 10 people

- Feeling sick and/or vomiting. If these occur, they are mainly experienced early on 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 will not last for more than a few days. If you have these effects, your doctor may recommend that you drink more liquids and, if necessary, may prescribe a medicine to stop you being sick.

Common: may affect up to 1 in 10 people

- weight loss
- decreased appetite
- feeling faint, or fainting (blackout)
- dizziness
- trembling
- headache
- feeling very sleepy with low energy
- abnormally tired
- stomach pain or discomfort
- diarrhoea
- indigestion
- muscle spasms
- falling
- high blood pressure
- feeling weak
- general feeling of being unwell
- seeing, feeling, or hearing things that are not real (hallucinations)
- feeling sad (depression)

- wounds (cuts)

Uncommon: may affect up to 1 in 100 people

- increased liver enzymes in the blood (laboratory test result that tells how well your liver is working)
- tingling, pricking, or numbness of the skin
- change in the sense of taste
- excessive sleepiness
- blurred vision
- ringing or buzzing in the ears (tinnitus)
- feeling the need to vomit (retch)
- muscle weakness
- excessive water loss in the body
- low blood pressure
- reddening of the face
- increased sweating

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 Acumor 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 and blister after the letters EXP. The expiry date refers to the last day of that month.

If your medicine is packaged in aluminium blister packs:

Store in the original package in order to protect from moisture.

If your medicine is packaged in plastic blister packs with aluminium foil lids:

Do not store above 25 °C. Store in the original package in order to protect from moisture.

If your medicine is packaged in a tablet container:

Do not store above 25 °C. Keep the container tightly closed and store in the original container in order to protect from moisture. Use within 3 months of opening.

If your medicine is packaged in a plastic bottle:

Keep the bottle tightly closed and store in the original bottle in order to protect from moisture.

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 Acumor XL contains:

The active substance is galantamine

- Acumor XL 8 mg prolonged release capsules contains 8 mg galantamine (as hydrobromide).
- Acumor XL 16 mg prolonged release capsules contains 16 mg galantamine (as hydrobromide).
- Acumor XL 24 mg prolonged release capsules contains 24 mg galantamine (as hydrobromide).

The other ingredients are:

Tablet core (contents of the capsule): Polyvinyl acetate, silica colloidal anhydrous, povidone, hydrogenated vegetable oil, sodium lauril sulfate and magnesium stearate.

Capsule Shell:

Gelatin, titanium dioxide (E171), allura red (E129)

Printing Ink: Shellac, propylene glycol, potassium hydroxide, black iron oxide (E172).

What Acumor XL looks like and contents of the pack

Acumor XL is available in three strengths, each of which can be recognised by its lettering:

Acumor XL 8 mg prolonged release capsules are hard gelatin capsules with a white body and pink cap, printed in black ink 'MYLAN' over 'GT8' on the body and the cap.

Acumor XL 16 mg prolonged release capsules are hard gelatin capsules with a white body and pale pink cap, printed in black ink 'MYLAN' over 'GT16' on the body and the cap.

Acumor XL 24 mg prolonged release capsules are hard gelatin capsules with a white body and pink cap, printed in black ink 'MYLAN' over 'GT24' on the body and the cap.

The 8 mg, 16 mg and 24 mg are available in:

- Plastic blister packs with an aluminium foil lid containing 7, 7 x 1 (unit dose), 10, 28, 28 x 1 (unit dose), 30, 30 x 1 (unit dose), 56, 84, 98 or 100 capsules, or calendar packs containing 28 and 28 x 1 (unit dose) capsules.
- Aluminium blister packs containing 7, 7 x 1 (unit dose), 10, 28, 28 x 1 (unit dose), 30, 30 x 1 (unit dose), 56, 84, 98 or 100 capsules, or calendar blister packs containing 28 and 28 x 1 (unit dose) capsules.
- Tablet containers containing 500 capsules.
- Bottles containing 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

Manufacturers

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft, Mylan utca 1, Komárom, 2900, Hungary

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