

Package leaflet: Information for the user
Conson XL 8 mg prolonged-release capsules, hard
Conson XL 16 mg prolonged-release capsules, hard
Conson XL 24 mg 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 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 Conson XL is and what it is used for
2. What you need to know before you take Conson XL
3. How to take Conson XL
4. Possible side effects
5. How to store Conson XL
6. Contents of the pack and other information

1. WHAT CONSON XL IS AND WHAT IT IS USED FOR

Conson XL 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 behavioral 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. Conson XL increases the amount of acetylcholine in the brain and treats the signs of the disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CONSON XL

Do not take Conson 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 or severe kidney disease

Warnings and precautions

Talk to your doctor or pharmacist before taking Conson XL.

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

Serious side effects

Conson XL can cause serious skin reactions, heart problems, fits (seizures). You must be aware of these side effects while you are taking Conson XL. See section 4.

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

- liver or kidney problems
- a heart disorder (such as chest discomfort that is often brought on by physical activity, heart attack, heart failure, slow or uneven heart beat, prolonged QTc interval)
- 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.

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

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

Children and adolescents

Conson XL is not recommended for children and adolescents.

Other medicines and Conson XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Conson XL 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 Conson 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).
- medicines affecting the QTc interval

Your doctor may give you a lower dose of Conson XL if you are also taking any of the medicines listed above.

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

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

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.

You should not breast-feed while you are taking Conson XL.

Driving and using machines

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

3. HOW TO TAKE CONSON 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 Conson XL prolonged-release capsules, carefully read the instructions under 'Switching from taking galantamine tablets or oral solution to galantamine capsules' in this section.

How much Conson XL to take

You will start treatment with Conson XL 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 Conson 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 and to discuss how you are feeling.

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

Switching from taking galantamine tablets or oral solution to galantamine capsules

If you are currently taking galantamine tablets or oral solution, your doctor may decide you should switch to Conson XL prolonged-release 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 Conson XL prolonged-release capsules.

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

How to take Conson XL

Conson XL must be swallowed whole and NOT chewed or crushed.

Take your dose of Conson XL once a day in the morning, with water or other liquids. Try to take Conson XL with food.

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

If you take more Conson XL than you should

If you take too much Conson XL, contact a doctor or hospital straight away. Take any remaining capsules and the packaging with you. The signs of overdose may include:

- severe nausea and vomiting
- weak muscle, slow heart beat, fits (seizures) and loss of consciousness.

If you forget to take Conson 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, contact your doctor.

If you stop taking Conson XL

Check with your doctor before you stop taking Conson 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.

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 Conson XL and see a doctor or go to your nearest emergency department immediately 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 Conson XL (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 Conson XL (may affect up to 1 in 10 people).

Fits (seizures). These are uncommon in people taking Conson XL (may affect up to 1 in 100 people).

You must stop taking Conson XL 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 medicines 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 the 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

Website: 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 CONSON 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 blister foil after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Conson XL contains:

- The active substance is galantamine. Each Conson XL 8 mg prolonged-release capsule, hard contains 8 mg galantamine (as hydrobromide). Each Conson XL 16 mg prolonged-release capsule, hard contains 16 mg galantamine (as hydrobromide). Each Conson XL 24 mg prolonged-release capsule, hard contains 24 mg galantamine (as hydrobromide).

- The other ingredients are:

Capsule content
Cellulose microcrystalline, Hypromellose, Ethylcellulose, Magnesium stearate

Capsule shell
8 mg: Gelatin, Titanium dioxide (E171)
16 mg: Gelatin, Titanium dioxide (E171), Red iron oxide (E172)
24 mg: Gelatin, Titanium dioxide (E171), Indigo carmine (E 132), Erythrosin (E 127), Red iron oxide (E 172), Yellow iron oxide (E 172)

What Conson XL looks like and contents of the pack

Conson XL prolonged-release capsules, hard are available in three strengths, each of which can be recognised by its colour:

8 mg: White capsules containing one round biconvex prolonged-release tablet
16 mg: Pale pink capsules containing two round biconvex prolonged-release tablets
24 mg: Orange capsules containing three round biconvex prolonged-release tablets

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

The capsules are available in the following blister packs:

7, 28, 30, 56, 84, 98, 100 prolonged-release capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pharmathen S.A.
Dervenakion 6, Pallini, Attiki, 153 51 Greece

Manufacturer
Pharmathen S.A.
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and


Pharmathen International S.A.
Industrial Park Sapes, Rodopi Prefecture,
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Distributed by
Dr. Reddy's Laboratories (UK) Ltd.,
6 Riverview Road, Beverley, East Yorkshire,
HU17 0LD, United Kingdom

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

Germany	Masparen 8mg, 16mg, 24mg Hartkapseln, retardiert
Netherlands	Masparen Retard 1x daags 8mg, 16mg, 24mg
Spain	Galantamina cinfa 8mg, 16mg, 24mg cápsulas duras de liberación prolongada EFG
United Kingdom	Conson XL 8 mg, 16 mg, 24 mg prolonged release capsules

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Brand:	Dr Reddy's
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