

PACKAGE LEAFLET: INFORMATION FOR THE USER

Exelon 1.5 mg hard capsules
Exelon 3.0 mg hard capsules
Exelon 4.5 mg hard capsules
Exelon 6.0 mg hard capsules
Rivastigmine

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 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.

In this leaflet:

1. What Exelon is and what it is used for
2. Before you take Exelon
3. How to take Exelon
4. Possible side effects
5. How to store Exelon
6. Further information

1. WHAT EXELON IS AND WHAT IT IS USED FOR

Exelon belongs to a class of substances called cholinesterase inhibitors.

Exelon is used for the treatment of memory disorders in patients with Alzheimer's disease.

Exelon is used for the treatment of dementia in patients with Parkinson's disease.

2. BEFORE YOU TAKE EXELON

Before taking Exelon it is important that you read the following section and discuss any questions you might have with your doctor.

Do not take Exelon

- if you are allergic (hypersensitive) to rivastigmine or any of the other ingredients of Exelon.
- if you have severe liver problems.

Take special care with Exelon

- if you have, or have ever had impaired kidney or liver function, irregular heartbeat, an active stomach ulcer, asthma or severe respiratory disease, difficulties in passing urine, or seizures (fits or convulsions).
- if you have not taken Exelon for several days, do not take the next dose until you have talked to your doctor.
- if you experience gastro-intestinal reactions such as nausea (feeling sick) and vomiting (being sick).
- if you have a low body weight.

- if you suffer from trembling.

If any of these apply to you, your doctor may need to monitor you more closely while you are on this medicine.

The use of Exelon in children and adolescents (age below 18 years) is not recommended.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have to undergo surgery whilst taking Exelon, you should inform the doctor before you are given any anaesthetics, because Exelon may exaggerate the effects of some muscle relaxants during anaesthesia.

Exelon should not be given at the same time as other medicines with similar effects to Exelon. Exelon might interfere with anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness).

Pregnancy and breast-feeding

It is preferable to avoid the use of Exelon during pregnancy, unless clearly necessary. Tell your doctor if you become pregnant during treatment. Women on Exelon should not breast-feed. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Your illness may impair your ability to drive or operate machinery and you must not carry out these activities unless your doctor tells you that it is safe to do so. Exelon may cause dizziness and somnolence, mainly at the start of treatment or when increasing the dose. If you experience such effects, you should not drive or operate machinery.

3. HOW TO TAKE EXELON

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

Swallow the capsules whole with a drink, without opening or crushing them.

You should take Exelon twice a day with food (in the morning and evening).

Your doctor will tell you what dosage of Exelon to take, starting with a low dose and gradually increasing, depending on how you respond to the treatment. The highest dose that should be taken is 6.0 mg twice a day. If you have not taken Exelon for several days, do not take the next dose until you have talked to your doctor.

To benefit from your medicine you should take it every day.

Tell your caregiver that you are taking Exelon.

This medicine should only be prescribed by a specialist and your doctor should regularly review whether it is having the desired effect. Your doctor will monitor your weight whilst you are taking this medicine.

If you take more Exelon than you should

Tell your doctor if you find you have accidentally taken more Exelon than you are told to. You may require medical attention. Some people who have accidentally taken too much Exelon have experienced nausea, vomiting, diarrhoea, high blood pressure and hallucinations. Slow heart beat and fainting may also occur.

If you forget to take Exelon

If you find you have forgotten to take your dose of Exelon, wait and take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

You may tend to get side effects most frequently when you start taking your medicine or increase to a higher dose. Side effects will gradually disappear most probably as your body becomes used to the medicine.

Very common side effects (affects more than 1 patient in 10) are dizziness, nausea (feeling sick), vomiting (being sick), diarrhoea, and loss of appetite.

Common side effects (affects 1 to 10 patients in 100) are: heartburn, stomach pain, headache, agitation, confusion, weakness, fatigue, sweating, a general feeling of being unwell, weight loss and trembling.

Uncommonly (affects 1 to 10 patients in 1,000), patients have complained of depression, difficulty in sleeping, changes in liver function, fainting or accidentally falling.

Rarely (affects 1 to 10 patients in 10,000), patients have experienced chest pain, seizures (fits or convulsions), rash, itching, gastric and intestinal ulcers.

Very rarely (affects less than 1 patient in 10,000), patients have experienced gastrointestinal haemorrhage (blood in stools or when vomiting), urinary tract infection, inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting), problems with heart rhythm (both fast and slow), high blood pressure, hallucinations, worsening of Parkinson's disease or development of similar symptoms (muscle stiffness, difficulty in carrying out movements).

Not known (frequency cannot be estimated from the available data): severe vomiting that can lead to a rupture of the oesophagus (the tube that connects the mouth with the stomach).

Patients with dementia associated with Parkinson's disease experience some side effects more frequently and also some additional side effects: trembling (very common), difficulty in sleeping, anxiety, restlessness, worsening of Parkinson's disease or development of similar symptoms (muscle stiffness, difficulty in carrying out movements), abnormally slow or uncontrollable movements, slow heart beat, too much saliva and dehydration (common), irregular heart beat and poor control of movements (uncommon).

Additional side effects which have been reported with Exelon transdermal patches: severe confusion, anxiety, fever (common).

Should such symptoms occur, contact your doctor as you may need medical assistance.

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.

5. HOW TO STORE EXELON

Keep out of the reach and sight of children.

Do not use Exelon after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

6. FURTHER INFORMATION

What Exelon contains

- The active substance is rivastigmine hydrogen tartrate.
- The other ingredients are hypromellose, magnesium stearate, microcrystalline cellulose, colloidal anhydrous silica, gelatin, yellow iron oxide (E172), red iron oxide (E172) and titanium dioxide (E171).

Each Exelon 1.5 mg capsule contains 1.5 mg of rivastigmine.

Each Exelon 3.0 mg capsule contains 3.0 mg of rivastigmine.

Each Exelon 4.5 mg capsule contains 4.5 mg of rivastigmine.

Each Exelon 6.0 mg capsule contains 6.0 mg of rivastigmine.

What Exelon looks like and contents of the pack

Exelon 1.5 mg hard capsules, which contain an off-white to slightly yellow powder, have a yellow cap and yellow body, with red imprint “EXELON 1,5 mg” on the body.

Exelon 3.0 mg hard capsules, which contain an off-white to slightly yellow powder, have an orange cap and orange body, with a red imprint “EXELON 3 mg” on the body.

Exelon 4.5 mg hard capsules, which contain an off-white to slightly yellow powder, have a red cap and red body, with a white imprint “EXELON 4,5 mg” on the body.

Exelon 6.0 mg hard capsules, which contain an off-white to slightly yellow powder, have a red cap and orange body, with a red imprint “EXELON 6 mg” on the body.

They are packed in blisters available in three different pack sizes (28, 56 or 112 capsules) and plastic bottles of 250 capsules, but these may not all be available in your country.

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Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>