

EXELON[®] CAPSULES

Rivastigmine (1.5mg, 3.0mg)

What is in this leaflet

1. What Exelon is used for
2. How Exelon works
3. Before you use Exelon
4. How to use Exelon
5. While you are using Exelon
6. Side effects
7. Storage and disposal of Exelon
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is Exelon used for

It is used for the treatment of memory disorders and dementia in people with Alzheimer's disease or with Parkinson's disease.

How Exelon works

Rivastigmine belongs to a class of substances called cholinesterase inhibitors.

In individuals with Alzheimer's dementia, certain nerve cells die in the brain, resulting in low levels of the neurotransmitter: acetylcholine (a substance that allows nerve cells to communicate with each other). This causes changes in the brain and problems with memory, thinking and behaviour. These problems gradually become worse with time.

Exelon works by preventing the breakdown of acetylcholine. This chemical is needed to help keep the brain working properly.

Rivastigmine helps to reduce the symptoms of Alzheimer's disease, to slow down the mental decline that happens in people with this condition, and helps to improve the ability to cope with everyday activities. It does not cure the condition.

Before you use Exelon

-When you must not use it

Do not take Exelon

- If you know that you are allergic (hypersensitive) to rivastigmine (the active substance in Exelon) or to any of the other ingredients listed at the end of this leaflet.

- If you have ever had an allergic reaction to a similar type of medicine. If any of these apply to you, do not take Exelon, and tell your doctor.

- Before you start to use it

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Warning and precautions

- If you experience gastrointestinal reactions such as nausea (feeling sick), vomiting (being sick) and diarrhoea. You may become dehydrated (losing too much fluid) if vomiting or diarrhoea are prolonged.
- If you have, or have ever had heart conditions such as irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have low potassium or magnesium,
- If you have, or have ever had difficulties in passing urine,
- If you have, or have ever had seizures (fits or convulsions),
- If you have, or have ever had asthma or severe respiratory disease,
- If you suffer from trembling,
- If you have a low body weight (less than 50 kg),
- If you have kidney or liver problems.

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

Exelon may cause increased gastric acid secretions. Care should be exercised in treating patients with active gastric or duodenal ulcers or patients predisposed to these conditions.

Read the following information before you take Exelon.

- Taking other medicines

Tell your doctor, pharmacist or healthcare provider about any other medicines you are taking or have recently taken, including any you have bought without a prescription.

Exelon should not be given at the same time as other medicines such as

- Medications with similar effects like cholinomimetic agents
- Anticholinergic medications such as oxybutynin, tolterodine (medication used to treat frequent urination)
- Metoclopramide (a medicine used to alleviate or prevent nausea and vomiting).
- Beta-blockers (medicines such as atenolol used to treat high blood pressure, angina, and other heart conditions).

If you have to undergo surgery whilst taking Exelon, you should inform your doctor before you are given any anaesthetics.

Caution when Exelon is taken together with medicinal product known to prolong the heart's electrical system (QT interval) (including but not limited to quinidine (medicine used to treat irregular heartbeat), amiodarone (medicine used to treat serious /fatal irregular heartbeat), pimozide (medicine works on central nervous system), halofantrine (antimalaria medicine), cisapride (medicine used to treat symptoms of night-time heartburn), citalopram (medicine used to treat depression), mizolastin (antihistamine medicine), medicine used to treat bacterial infection such as moxifloxacin, erythromycin). Your doctor may also monitor your clinical condition as needed.

- Exelon with food and drink

You should take Exelon twice a day, once with your breakfast and once with your evening meal.

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

- Older people (age 65 years and over)

Exelon can be used by the elderly.

- Children and adolescents (age below 18 years)

The use of Exelon in children and adolescents has not been studied and is therefore not recommended.

- Pregnancy and breast-feeding

In the event of pregnancy, the benefits of Exelon must be assessed against the possible effects on your unborn child.

Tell your doctor if you are pregnant or planning to become pregnant.

Ask your doctor, pharmacist or healthcare provider for advice before taking any medicine during pregnancy.

You should not breast-feed during treatment with Exelon.

Ask your doctor, pharmacist or healthcare provider for advice before taking any medicine while you are breast-feeding.

How to use Exelon

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

Do not exceed the recommended dose prescribed by your doctor.

- How much to use

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 mg twice a day.

- When and how to use it

You should take Exelon twice a day, once with your breakfast and once with your evening meal. Taking Exelon at the same time each day will help you remember when to take your medicine.

- How long to use it

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

Tell your caregiver that you are

taking Exelon.

The prescription of this medicine needs specialized advice before its initiation and a periodic assessment of therapeutic benefits. Your doctor will also monitor your weight whilst you are taking this medicine.

If you have questions about how long to take Exelon, talk to your doctor, pharmacist or healthcare provider.

- If you forget to use it

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 of Exelon to make up for the one that you missed.

- If you use too much (overdose).

Tell your doctor if you find you have accidentally taken more Exelon than you are instructed to. You may require medical attention. Some people who have accidentally taken too much Exelon have experienced nausea, vomiting, diarrhoea, abdominal pain, dizziness, trembling, headache, drowsiness, confusional state, excessive sweating, high blood pressure and hallucinations. Slow heart beat and fainting may also occur.

While you are using it

- Things you must do

If you have not been taking Exelon for more than three days do not take the next dose until you have talked to your doctor.

- Things you must not do

Do not stop taking Exelon or change your dose without talking with your doctor.

- Things to be careful of

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Exelon may cause dizziness and sleepiness, mainly at the start of treatment or when increasing the dose. Therefore, you should wait to know what effects Exelon may cause before engaging in such activities. If you feel dizzy or drowsy, do not

drive, use machines or perform any other tasks that require your attention.

Side effects

As with all medicines, individuals taking Exelon may experience side effects, although not everybody gets them.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Very common (may affect more than 1 in 10 people): feeling sick (nausea), being sick (vomiting), diarrhoea, dizziness and loss of appetite.

Common (may affect up to 1 in every 10 people): agitation, confusion, nightmares, anxiety, headache, drowsiness, trembling, stomach pains, indigestion, excessive sweating, fatigue, a general feeling of being unwell, weight loss.

- Some side effects could be serious

Uncommon (may affect up to 1 in every 100 people): depression, fainting.

Rare (may affect up to 1 in every 1,000 people): fits, chest pain, heart attack, gastric and duodenal ulcers.

Very rare (may affect up to 1 in every 10,000 people): hallucinations (see, hear, smell, taste or feel things that do not exist), problems with heart rhythm, blood in stools or when vomiting, severe upper stomach pain, often with nausea and vomiting (inflammation of the pancreas), severe vomiting that can lead to a rupture of the oesophagus.

Frequency not known: losing too much fluid (dehydration), yellowing of skin or the whites of eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite (liver disorders), skin inflammation, blisters or swelling of the skin that are

increasing and spreading, stiff limbs, trembling hands (extrapyramidal symptoms).

If you experience any of these, stop taking Exelon and tell your doctor straight away.

Additional side effects which have been reported with Exelon Patch

Common (may affect up to 1 in every 10 people): inability to retain adequately urine.

In addition, you should contact your doctor, pharmacist or healthcare provider if you experience any other possible side effects not mentioned in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Exelon

- Storage

- Do not use Exelon after the expiry date shown on the box.
- Store below 30°C.
- Store Exelon in the original package.
- Do not use any Exelon pack that is damaged or shows signs of tampering.
- Keep Exelon out of the reach and sight of children.

- Disposal

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.

Product Description

- What it looks like

Hard capsules

Exelon 1.5 mg :

Colour: Yellow opaque.

Imprint: Red imprint on body, radial “EXELON 1.5mg”

Exelon 3.0 mg :

Colour: Orange opaque.

Imprint: Red imprint on body, radial “EXELON 3mg”.

- Ingredients

-Active ingredient: Rivastigmine

-Inactive ingredients:

methylhydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, colloidal silica, gelatin, yellow iron oxide (E 172), red iron oxide (E 172), and titanium dioxide (E 171).

- MAL numbers

- Exelon 1.5mg capsules: MAL 19990976ACRZ
- Exelon 3.0mg capsules: MAL 19990977ACRZ

Manufacturer

Siegfried Barbera S.L.,
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Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.

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