

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

EXELON®

1.5 mg, 3 mg, 4.5 mg, 6 mg Capsules

Active ingredient:

Each capsule contains Rivastigmine (as hydrogen tartrate) 1.5 mg, 3 mg, 4.5 mg, 6 mg

Inactive ingredients:

See section 6 'Further Information'.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of patients with mild to moderate-severe Alzheimer's-type dementia, also called Alzheimer's disease.

For the treatment of the symptoms of mild to moderate-severe Alzheimer's disease dementia.

For symptomatic treatment of mild to moderate-severe dementia associated with Parkinson's disease.

Rivastigmine belongs to a class of substances called cholinesterase inhibitors. In patients with dementia as a result of either Alzheimer's or Parkinson's disease, certain nerve cells in the brain die, causing low levels of the neurotransmitter acetylcholine (a substance that allows nerve cells to communicate with each other). Rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, Exelon allows levels of acetylcholine in the brain to be increased, helping to reduce the symptoms of Alzheimer's disease and dementia associated with Parkinson's disease.

Exelon is intended for the treatment of adult patients with mild to moderate-severe Alzheimer's disease dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behavior. The capsules can also be used for the treatment of dementia in adult patients with Parkinson's disease.

Therapeutic group:

Cholinesterase inhibitors.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to rivastigmine (the active ingredient of Exelon), carbamate derivatives or to any of the additional ingredients contained in the medicine, listed in section 6.
 - you have had a skin reaction while using the Exelon patch, that spread beyond the Exelon patch size, if you had an intense local reaction (such as blisters, increased skin inflammation, swelling) and if this condition did not improve within 48 hours after removal of the patch.
- If these conditions apply to you, **notify the doctor and do not take Exelon.**

Special warnings regarding use of the medicine

Before treatment with Exelon, tell the doctor if:

- you have, or have ever had, an irregular or slow heartbeat.
- you have, or have ever had, an active stomach ulcer.
- you have, or have ever had, difficulties in passing urine.
- you have, or have ever had, seizures.
- you have, or have ever had, asthma or a severe respiratory disease.
- you have, or have ever had, impaired kidney function.
- you have, or have ever had, impaired liver function.
- you suffer from trembling.
- you have a low body weight.

- you have gastrointestinal reactions such as a sick feeling of nausea, vomiting and diarrhea. You may become dehydrated (due to loss of too much fluid), if the vomiting or diarrhea persist.

If any of these apply to you, your doctor may need to monitor you more closely during the course of treatment with the medicine.

If you have not taken Exelon for more than three days, do not resume taking the medicine without consulting with the attending doctor.

Children and adolescents

Use of Exelon is not relevant for the treatment of Alzheimer's disease in children.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Do not take Exelon at the same time as other medicines with effects similar to Exelon.

Exelon may interfere with anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness). Do not take Exelon together with metoclopramide (a medicine used to relieve or prevent nausea and vomiting). Taking the two medicines together may cause problems such as stiff limbs and trembling hands.

If you are about to undergo surgery while taking Exelon, inform the doctor before you are given any anesthetics as Exelon can increase the effects of some muscle relaxants during anesthesia.

Caution should be exercised when Exelon is taken together with beta-blockers (medicines such as atenolol used to treat hypertension, angina pectoris and other heart conditions).

Taking the two medicines together may cause problems such as slow heartbeat (bradycardia) that may result in fainting or loss of consciousness.

Use of Exelon and food

Take Exelon twice a day, once with breakfast and once with dinner.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you are pregnant or are planning a pregnancy, ask your doctor or pharmacist for advice before taking the medicine.

There is no information about use of the medicine in pregnant women. If you are pregnant, the benefits of using Exelon should be assessed against the possible effects on your unborn child.

Do not use Exelon during pregnancy, unless its use is absolutely necessary.

It is not known whether Exelon is secreted into breast milk; therefore, do not breast-feed during treatment with Exelon.

Driving and operating machinery

The doctor will tell you whether your illness allows you to drive a car and safely operate machinery. Exelon may cause dizziness and somnolence, mainly at the start of treatment or when increasing the dosage. If you feel dizzy or sleepy, do not drive, operate machinery or engage in any activity that requires concentration.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

How to start treatment?

The dosage and the treatment regimen will be determined by the doctor only.

- Treatment generally begins with a low dose.
- The doctor will gradually increase your dose, depending on your response to the treatment.
- The highest dose that should be taken is 6 mg twice a day.

During the course of treatment, the doctor will regularly check if your medicine is working for you. The doctor will also monitor your weight while you are taking the medicine. If you have not taken Exelon for more than three days, do not take the next dose until you consult with your doctor.

Do not exceed the recommended dosage.

Treatment duration -

- Tell your caregiver that you are taking Exelon.
- To benefit from the medicine, take the medicine every day.
- Take Exelon twice a day, in the morning and evening, with food.

Method of administration

- Do not chew! Swallow the capsules whole with a drink.
- Do not open or crush the capsules.

If you took a higher dosage of Exelon than required, tell your doctor. You may require medical supervision. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

There have been patients who accidentally took an overdose of Exelon and showed signs of feeling malaise: nausea, vomiting, diarrhea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur.

If you forget to take Exelon

If you forgot to take your Exelon dose at the scheduled time, do not take a double dose to compensate for the forgotten dose. Take the next dose at the scheduled time. If you have further questions regarding use of the medicine, ask your doctor or the pharmacist.

Adhere to the treatment regimen as recommended by your doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Exelon may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. The frequency of side effects may be higher at the beginning of treatment or when increasing the dose of the medicine. The side effects will most probably disappear gradually as the body gets used to the medicine.

Very common side effects (may occur in more than 1 in 10 users):

- Dizziness
- Loss of appetite
- Stomach problems such as feeling sick (nausea) or being sick (vomiting), diarrhea

Common side effects (may occur in up to 1 in 10 users):

- Anxiety
- Sweating
- Headache
- Heartburn
- Weight loss
- Stomach pain
- Feeling agitated
- Feeling tired or weak
- Generally feeling unwell
- Trembling or feeling confused
- Loss of appetite
- Nightmares

Uncommon side effects (may occur in up to 1 in 100 users):

- Depression
- Difficulty sleeping
- Fainting or accidental falls
- Changes in liver function

Rare side effects (may occur in up to 1 in 1,000 users):

- Chest pain
- Rash, itching
- Fits
- Ulcers in the stomach or intestine

Very rare side effects (may occur in up to 1 in 10,000 users):

- High blood pressure

- Urinary tract infection
- Hallucinations
- Heartbeat problems, such as: fast or slow heartbeat
- Bleeding in the intestines – shows as blood in stools or when vomiting
- Inflammation of the pancreas – symptoms include severe upper stomach pain, often with nausea or vomiting
- Worsening of Parkinson's disease symptoms or development of similar symptoms – such as stiff muscles, difficulty in carrying out movements

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Being violently sick, with vomiting that can cause tearing of the oesophagus, a tube that connects the mouth and the stomach
- Dehydration (loss of a lot of fluid)
- Liver disorders (yellow skin, yellowing of the whites of the eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and lack of appetite)
- Aggression, feeling restless
- Irregular heartbeat

Patients with Parkinson's disease-associated dementia:

In these patients, side effects are more common. They also have some additional side effects:

Very common side effects (may occur in more than 1 in 10 users):

- Trembling
- Fainting
- Accidental falls

Common side effects (may occur in up to 1 in 10 users):

- Anxiety
- Feeling restless
- Slow heartbeat
- Difficulty sleeping
- Too much saliva and dehydration
- Unusually slow movements or movements that cannot be controlled
- Worsening of Parkinson's disease symptoms or development of similar symptoms, such as stiff muscles, difficulty in carrying out movements and muscle weakness

Uncommon side effects (may occur in up to 1 in 100 users):

- Irregular heartbeat and poor control of movements.

Other side effects that have been reported with Exelon patches and which may also occur with the capsules:

Common side effects (may occur in up to 1 in 10 users):

- Fever
- Severe confusion
- Urinary incontinence (lack of control of passing urine)

Uncommon side effects (may occur in up to 1 in 100 users):

- Hyperactivity (high level of activity, restlessness)

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Localized allergic reaction when a patch was used, such as blisters or skin inflammation

If you experience any of these side effects, refer to your doctor as you may need medical assistance.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <http://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not dispose of medicines in waste water or a household waste bin. Ask the pharmacist how to dispose of medicines that are no longer needed. These measures will protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, rivastigmine hydrogen tartrate, the medicine also contains:

Microcrystalline cellulose, Hypromellose, Magnesium stearate, Silica, colloidal anhydrous, Gelatin, Titanium dioxide (E171), Yellow iron oxide (E172), Red iron oxide (E172), Shellac.

What the medicine looks like and the contents of the package

- Exelon 1.5 mg hard capsules containing an off-white to slightly yellow powder. The color of the capsule cap and body is yellow. "EXELON 1.5 mg" is imprinted in red on the body of the capsule.
- Exelon 3 mg hard capsules containing an off-white to slightly yellow powder. The color of the capsule cap and body is orange. "EXELON 3 mg" is imprinted in red on the body of the capsule.
- Exelon 4.5 mg hard capsules containing an off-white to slightly yellow powder. The color of the capsule cap and body is red. "EXELON 4.5 mg" is imprinted in white on the body of the capsule.
- Exelon 6 mg hard capsules containing an off-white to slightly yellow powder. The color of the capsule cap is red and the body is orange. "EXELON 6 mg" is imprinted in red on the body of the capsule.

All dosages are marketed in packages of 28 capsules.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in March 2021 according to MOH guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Exelon 1.5 mg –	110 66 29189
Exelon 3 mg –	110 67 29190
Exelon 4.5 mg –	110 68 29191
Exelon 6 mg –	110 69 29192