

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

The medicine is dispensed with a doctor's prescription only

**EXELON® PATCH 5  
EXELON® PATCH 10  
EXELON® PATCH 15**

**Transdermal Patch**

**The active ingredient:**

Each patch contains:

**Exelon Patch 5:** A 5 cm² transdermal patch that contains 9 mg rivastigmine. The release rate of the medicine is: 4.6 mg in 24 hours.

**Exelon Patch 10:** A 10 cm² transdermal patch that contains 18 mg rivastigmine. The release rate of the medicine is: 9.5 mg in 24 hours.

**Exelon Patch 15:** A 15 cm² transdermal patch that contains 27 mg rivastigmine. The release rate of the medicine is: 13.3 mg in 24 hours.

**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?**

Exelon Patch 5 and Exelon Patch 10: For treatment of mild to moderate Alzheimer's dementia (memory disorders).

Exelon Patch 15: For treatment of Alzheimer's dementia (memory disorders). Proven efficacy in patients with mild, moderate and severe Alzheimer's disease.

**Therapeutic group:** Cholinesterase inhibitors (anticholinesterases)

Rivastigmine belongs to a class of substances called cholinesterase inhibitors. In patients with Alzheimer's dementia, 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.

Exelon is intended for the treatment of adult patients with mild, moderate and severe dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behavior.

**2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient rivastigmine or to any of the additional ingredients contained in the medicine, listed in section 6 'Further Information'
- you have ever had an allergic reaction to a similar type of medicine (carbamate derivatives)
- you had a skin reaction that spread beyond the patch size, if there was 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, inform the doctor and do not use Exelon Patch.

**Special warnings regarding use of the medicine**

**Before treatment with Exelon Patch, tell the doctor if:**

- you have, or have ever had, a heart condition, such as an irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have a low blood level of potassium or magnesium
- 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 suffer from trembling
- you have a low body weight

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

In these cases, your doctor may monitor your condition more closely during treatment with the medicine.

If you have not applied an Exelon Patch for more than three days, do not apply the next patch without consulting the attending doctor.

**Children and adolescents**

Exelon Patch is not intended for use in children.

**Drug interactions**

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

- Exelon may interfere with anticholinergic medicines, some of which are used to relieve stomach cramps or spasms (such as dicyclomine), for treatment of Parkinson's disease (such as amantadine) or for prevention of motion sickness (such as diphenhydramine, scopolamine or meclizine)
- Do not use Exelon Patch 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 during treatment with Exelon Patch, inform your doctor that you are using this medicine, as the Exelon Patch may increase the effects of some muscle relaxants during anesthesia
- Exercise caution when using Exelon Patch together with beta-blockers (medicines such as atenolol used to treat hypertension, angina pectoris and other heart conditions). Use of the two medicines together may cause problems, such as slowing of the heartbeat (bradycardia) leading to fainting or loss of consciousness
- Exercise caution when Exelon is taken together with other medicines that can affect your heart rhythm or the electrical system of the heart (QT prolongation)

**Using the medicine with food**

Exelon Patch may be used with food and drink.

**Using the medicine and alcohol consumption**

Exelon Patch may be used with alcohol.

**Pregnancy, breast-feeding and fertility**

- If you are pregnant or breast-feeding, think you are pregnant or are planning a pregnancy, consult your doctor or pharmacist before using the medicine
- There is no information about use of Exelon in pregnant women. If you are pregnant, the benefits of using Exelon Patch should be assessed against the possible effects on the unborn baby. Do not use Exelon Patch during pregnancy unless its use is clearly necessary
- Do not breast-feed during treatment with Exelon Patch. It is not known whether Exelon is secreted into breast milk

**Driving and using machines**

Your doctor will advise you on whether your illness allows you to safely drive vehicles and operate machinery. Exelon Patch may cause fainting or severe confusion. If you feel faint or confused, do not drive a vehicle, use machines or perform any task that requires alertness.

**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.

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

**Important:**

- **Take off the previous patch before putting ONE new patch on**
- **Only one patch per day**
- **Do not cut the patch into pieces**
- **Press the patch firmly with the palm of your hand for at least 30 seconds**
- **For external use only**

**How to start the treatment?**

- Your doctor will tell you which Exelon Patch is most suitable for you.
- Treatment usually starts with Exelon Patch 5 (4.6 mg per 24 hours)
- The usual recommended daily dose is Exelon Patch 10 (9.5 mg per 24 hours). If well tolerated, the doctor may increase the dose to Exelon Patch 15 (13.3 mg per 24 hours)

- Use only one patch at a time and replace the patch with a new one after 24 hours

During the course of the treatment, your doctor may adjust the dose to suit your individual needs.

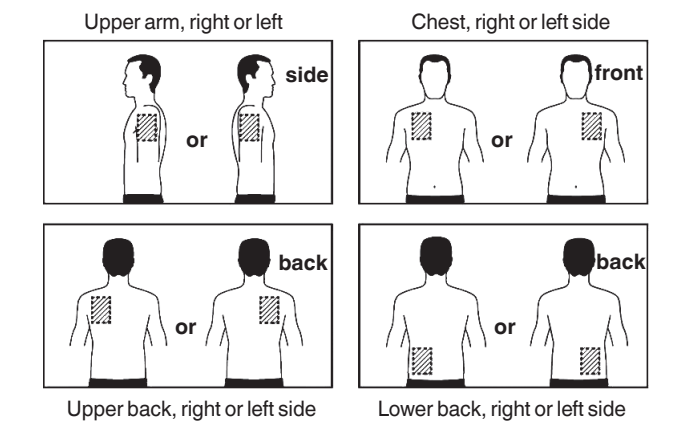
**Do not exceed the recommended dose.**

If you have not applied Exelon Patch for more than three days, do not apply the next patch before consulting your doctor. Patch treatment can be resumed at the same dose if the treatment was not interrupted for more than three days. Otherwise, your doctor will restart your treatment with Exelon Patch 5 (4.6 mg per 24 hours).

**Where to apply Exelon Patch?**

- Before applying a patch, make sure that the skin is clean, dry and hairless, free of any powder, oil, moisturizer or lotion that could keep the patch from sticking to the skin properly, free of cuts, rashes and/or irritations
- **Carefully remove an existing patch before putting on a new one.** If multiple patches are applied to your body, your body may be exposed to an excessive amount of the medicine, a situation that can be dangerous
- Apply **ONLY ONE** patch per day to **ONLY ONE** of the possible locations shown in the following figures:
  - left upper arm **or** right upper arm
  - upper left **or** upper right side of the chest (**avoid applying the patch to the breast**)
  - upper left **or** upper right side of the back
  - lower left **or** lower right side of the back

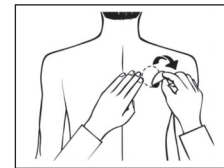
**Every 24 hours, take off the existing patch before putting ONE new patch onto ONLY ONE of the following possible locations:**



When changing the patch, you must remove the previous day's patch before you apply the new one, each time to a different location on the skin (for example, on the right side of your body one day, and on the left side the next day, on the upper part of the body on one day and the lower part of the body the next day). Do not apply a new patch in the exact same area twice within 14 days.

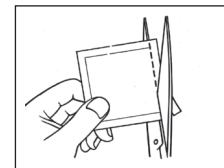
**How to apply Exelon Patch?**

The patch is thin, opaque, plastic and sticks to the skin. Each patch is sealed in a closed sachet that protects it until you are ready to put it on. Do not open the sachet or remove the patch until just before applying it.

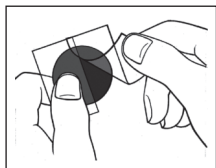


Carefully remove the existing patch before putting on a new one.

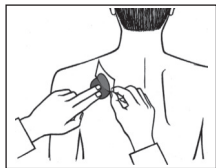
For patients starting treatment for the first time and for patients restarting treatment after treatment interruption, please begin with the second picture.



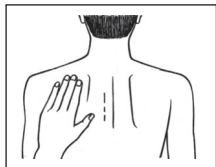
- Each patch is sealed in a closed, protective sachet. Only open the sachet when you are ready to use the patch. Cut the sachet along the dotted line with scissors and remove the patch from the sachet.



- A protective liner covers the sticky side of the patch. Peel off one side of the protective liner and do not touch the sticky part of the patch with the fingers.



- Put the sticky side of the patch on the upper or lower back, upper arm or chest and then peel off the second part of the protective liner.



- Now press the patch firmly for at least 30 seconds using the palm of the hand, to make sure that the edges stick well.

If it helps you, you may write, for example, the day of the week on the patch with a thin ball point pen.

Leave the patch in place continuously until it is time to replace it with a new one. You may wish to experiment with different locations when applying a new patch to find the places that are most comfortable for you and where clothing will not rub against the patch.

**How to remove Exelon Patch?**

Gently and slowly pull at one edge of the patch to remove it from the skin.

In case adhesive residue is left on the skin, gently wet the area with warm water and a mild soap or use baby oil to remove it. Do not use alcohol or other dissolving liquids (nail polish remover or other solvents).

Wash your hands with soap and water after removing the patch. In case of contact with the eyes or if the eyes become red after handling the patch, rinse the eyes immediately with plenty of water and seek medical assistance if symptoms do not resolve.

**Can the patch be worn when bathing, swimming, or during exposure to the sun?**

- Bathing, swimming, or showering should not affect the patch. Make sure that the patch does not loosen during these activities.
- Do not expose the patch to any external heat sources (e.g., excessive sunlight, saunas, solarium) for long periods of time.

**What to do if the patch falls off?**

If the patch falls off, apply a new one for the rest of the day, and then replace it the next day at the usual time.

**When and for how long to apply Exelon Patch?**

- To benefit from treatment, you must apply a new patch every day; it is preferable to replace the patch at the same time each day.
- Only wear one patch at a time and replace it with a new one after 24 hours.

**If you accidentally apply more Exelon Patches than required**

If you accidentally applied more than one patch, remove all the patches from your skin, and then inform the attending doctor that you have accidentally applied more than one Exelon Patch.

You may require medical supervision. Some people who have accidentally taken too much Exelon experienced nausea, vomiting, diarrhea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur.

If you took an overdose or if a child has accidentally swallowed the medicine, or applied a patch on his body, refer immediately to a doctor or proceed to an emergency room and bring the package of the medicine with you.

**If you forget to apply Exelon Patch**

If you find that you have forgotten to apply an Exelon Patch, apply a new patch immediately. You may apply the next patch at the usual time the next day. Do not apply two patches together to make up for the one that was forgotten.

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

**If you stop using Exelon Patch**

Tell the doctor or pharmacist if you stop using the patch.

**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 pharmacist.**

**4. SIDE EFFECTS**

As with any medicine, use of Exelon Patch 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 is higher when beginning treatment or when increasing the dosage of the medicine. In most cases, the side effects will gradually disappear, as the body gets used to the medicine.

**Take off the patch and inform the attending doctor immediately if you experience any of the following side effects which could become serious:**

- **Common side effects** (effects that occur in 1-10 in 100 users):
  - Loss of appetite
  - Feeling dizzy
  - Feeling agitated or sleepy
  - Urinary incontinence (inability to pass urine properly)

- **Uncommon side effects** (effects that occur in 1-10 in 1,000 users):
  - Problems with your heartbeat, such as a slow heartbeat
  - Seeing things that are not really there (hallucinations)
  - Stomach ulcer
  - Dehydration (losing too much fluid)
  - Hyperactivity (high level of activity, restlessness)
  - Aggression

- **Rare side effects** (effects that occur in 1-10 in 10,000 users):
  - Falling

- **Very rare side effects** (effects that occur in less than 1 in 10,000 users):
  - Stiff arms or legs
  - Trembling hands

**Side effects of unknown frequency** (the frequency of these effects has not been established yet):

- Allergic reaction where the patch was applied, such as blisters or inflamed skin
- Worsening of signs of Parkinson's disease - such as tremor, stiffness and shuffling
- Inflammation of the pancreas - the signs include serious upper stomach pain, often accompanied with nausea or vomiting
- Fast or uneven heartbeat
- High blood pressure
- Fits (seizures)
- Liver disorders (yellow skin, yellowing of the whites of the eyes, abnormal dark urine or unexplained nausea, vomiting, tiredness and loss of appetite)

- Changes in results of tests which show how well the liver is functioning
- Feeling restless
- Nightmares

Take off the patch and refer to your doctor immediately if you experience any of the above side effects.

**Other side effects reported for Exelon capsules or Exelon oral solution and which may occur with the patches:**

**Common side effects** (effects that occur in 1-10 in 100 users): Excess saliva, loss of appetite, feeling restless, feeling generally unwell, trembling or feeling confused, excessive sweating.

**Uncommon side effects** (effects that occur in 1-10 in 1,000 users): Uneven heart rate (e.g., fast heart rate), difficulty sleeping, accidental falls.

**Rare side effects** (effects that occur in 1-10 in 10,000 users): Fits (seizures), an ulcer in the intestine, chest pain that may be caused by heart spasm.

**Very rare side effects** (effects that occur in less than 1 in 10,000 users): High blood pressure, inflammation of the pancreas - the signs include serious upper stomach pain, often with nausea or vomiting, bleeding in the gut - shows as blood in stools or when vomiting, seeing things that are not there (hallucinations). Some of the people who suffered from severe vomiting have had tearing of the esophagus that connects the mouth with the stomach.

**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 the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs to the online form for reporting side effects, or by entering the link: https://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 in order 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.

**Storage conditions:**

- Store below 25°C
- Keep the patch in the sachet until use
- Do not use the patch if it is damaged or if there are signs of opening
- After removing the patch, fold it in half, with the sticky sides facing inward and press them together. Return the used patch to its sachet and dispose of it in such a way that children will not be able to handle it. Do not touch your eyes with your fingers; wash your hands with soap and water after removing the patch. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

**6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

Acrylic pressure-sensitive adhesive; silicone pressure-sensitive adhesive; poly (butylmethacrylate, methylmethacrylate); silicone oil 12,500 cSt, dimethicone; tocopherol (all-rac-α), vitamin E

**What the medicine looks like and the contents of the package:** The package includes sachets, with one Exelon Patch in each sachet.

The patch is a thin, transdermal patch comprising three layers. The outer layer is beige and labeled with:

Exelon Patch 5: AMCX

Exelon Patch 10: BHD1

Exelon Patch 15: CNFU

Package sizes: Exelon Patch 5, Exelon Patch 10: 3, 7, 30, 60 patches.

Exelon Patch 15: 7, 30 patches.

Not all pack sizes may be marketed.

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

Revised in July 2023 according to MOH guidelines.

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

**Exelon Patch 5:** 139 69 31674

**Exelon Patch 10:** 139 70 31675

**Exelon Patch 15:** 150 97 33884