

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 memory (dementia) disorders.

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

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.

Therapeutic group:

Cholinesterase inhibitors (anticholinesterases)

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 Patches.

Special warnings regarding use of the medicine

Before treatment with Exelon Patch, tell the doctor if:

- you have, or have had, an irregular or slow heartbeat
- you have, or have had, an active stomach ulcer
- you have, or have had, difficulties in passing urine
- you have, or have had, seizures
- you have, or have 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.

Do not use Exelon at the same time as other medicines with an effect similar to that of Exelon.

- 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 Patches, 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 slow heartbeat (bradycardia) that may result in fainting or loss of consciousness

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 operating machinery

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 or operate machinery. Avoid any activity that requires alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with your 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.

Initiation of treatment and supervision of the treatment will be undertaken by a doctor experienced in diagnosis and treatment of Alzheimer's dementia. The diagnosis should be performed according to current guidelines. As with any treatment initiation for patients with dementia, therapy with rivastigmine should only be started if there is a caregiver available for regular administration and monitoring of treatment.

Important:

- **Remove the previous patch before applying one new patch**
- **Use only one patch each day**
- **Do not cut the patch into pieces**
- **When applying the patch, press firmly with the palm of your hand for at least 30 seconds**
- **Do not exceed the recommended dosage**
- **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 dosage 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

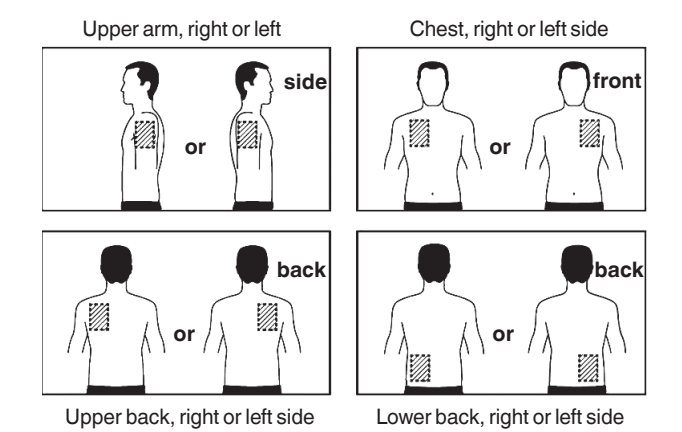
During the course of the treatment, your doctor may adjust the dosage to suit your individual needs.

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

Where to apply Exelon Patch?

- Before applying Exelon 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, and 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 following locations shown in the figures below:
 - 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 a new patch onto only one of the following locations:

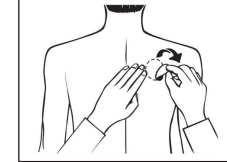


When changing the patch, you must remove the previous day's patch before you apply the new one, each time to a different location on the skin (for example, on the right side of your body one day, and on the left side the next day, on the upper part of the body on one day and the lower part of the body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

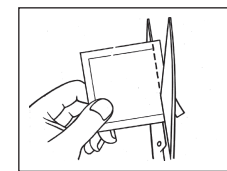
How to apply Exelon Patch?

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.

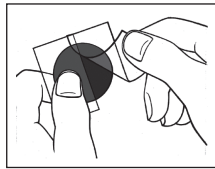
Carefully remove the existing patch before putting on a new one.



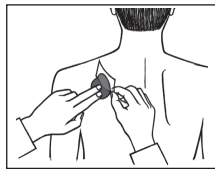
For patients starting treatment for the first time and for patients restarting treatment after an interruption of treatment, please begin with the second picture.



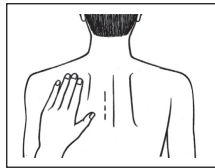
- Each patch is sealed in a closed, protective sachet. Only open the sachet when you are ready to use the patch. Cut the sachet with a scissor, along the dotted line and remove the patch.



- A protective liner covers the sticky side of the patch. Peel off one side of the protective liner; 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 remember, you may write, e.g., 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 treatment with the patch, rinse the eyes immediately with plenty of water. If the symptoms are not resolving, seek medical assistance.

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 your medicine, 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 felt sick: nausea, vomiting, diarrhea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur. If a child accidentally applied an Exelon Patch, immediately refer 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.

If you stop using Exelon Patch

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Refer to and 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 patch and inform the attending doctor immediately if you experience one or more of these effects that may be serious:

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

Uncommon side effects (effects that occur in up to 1 in 100 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 up to 1 in 1,000 users):

- Falls

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

- Stiff hands or legs
- Trembling hands

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

- Allergic reaction where the patch was applied, such as blisters and inflamed skin
- Worsening of signs of Parkinson's disease - such as tremor, stiffness and shuffling
- Inflammation of the pancreas - signs include serious upper stomach pain, generally accompanied by malaise including nausea and vomiting
- Fast and uneven heartbeat
- High blood pressure
- Fits
- 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 and which may occur with the patches:

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

Uncommon side effects (effects that occur in up to 1 in 100 users): Uneven heart rate (e.g. fast heart rate), difficulty sleeping, accidental falls.

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

Very rare side effects (effects that occur in up to 1 in 10,000 users): High blood pressure, inflammation of the pancreas - the signs include serious upper stomach pain, generally accompanied by malaise with nausea and vomiting, bleeding in the gut - bloody stools or vomit, seeing things that do not exist (hallucinations).

Some of the people who suffered from severe vomiting, 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 on 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
- Store below 25°C
- Store the patch in its 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. Ask the pharmacist how to dispose of patches that have been used or are no longer needed. Used patches should be discarded in their original package
- Store in the original packaging

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: BHDI

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 March 2021 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