

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

Active ingredient:

Each patch contains:

Exelon Patch 5: each 5 cm² transdermal patch contains 9 mg rivastigmine. The release rate of the medicine is: 4.6 mg/24 h.

Exelon Patch 10: each 10 cm² transdermal patch contains 18 mg rivastigmine. The release rate of the medicine is: 9.5 mg/24 h.

Exelon Patch 15: each 15 cm² transdermal patch contains 27 mg rivastigmine. The release rate of the medicine is: 13.3 mg/24 h.

Inactive ingredients:

See section 6 'Further Information'.

Read this 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: Treatment of mild to moderate memory disorders and dementia in patients with Alzheimer's disease.

Exelon Patch 15: Treatment of mild to severe memory disorders and dementia in patients with Alzheimer's disease.

In patients with dementia resulting from Alzheimer's disease, 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).

Rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, Exelon allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's disease.

Therapeutic group:

Brain selective cholinesterase inhibitor

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- You know that you are hypersensitive (allergic) to the active ingredient rivastigmine or to other carbamate derivatives or to any of the other ingredients of the medicine listed in section 6 'Further Information'.
- If you had a skin reaction which spread beyond the patch size**, if there was a more intense local reaction (such as blisters, increasing skin inflammation, swelling) and if this condition did not improve within 48 hours after removal of the patch.

If these conditions apply to you, **tell your doctor without applying the preparation.**

Special warnings regarding use of the medicine

Before beginning treatment with Exelon Patch, tell the doctor:

- if you experience gastrointestinal reactions such as nausea, vomiting and diarrhea. You may become dehydrated (losing too much fluid) if vomiting or diarrhea are prolonged.
- if you suffer or have ever suffered from an irregular heartbeat, stomach ulcer, difficulties in passing urine, seizures, asthma or a severe respiratory disease.
- if you suffer from trembling, low body weight (less than 50 kg), or from impaired liver function.

In these cases, the doctor will need to monitor you more closely while you are on this medicine.

Talk to your doctor right away if you have skin inflammation, blisters or swelling of the skin that are increasing and spreading.

If you have not applied Exelon Patch for more than 3 days do not resume applying the next patch without consulting the attending doctor.

❗ Taking other medicines

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 Patch should not be used together with:

- medicines with similar action (cholinergic agents)
- anticholinergic medicines (such as medicines used to relieve stomach cramps or spasms, to treat Parkinson's or to prevent travel sickness)
- Exelon Patch should not be used together with metoclopramide (a medicine used to alleviate or prevent nausea and vomiting). There may be additive effects such as stiff limbs and trembling hands
- If you about to undergo surgery or any other procedure that involves anaesthesia, you should inform your anaesthesiologist that you are taking this medicine, because Exelon Patch may exaggerate the effects of some muscle relaxants during anaesthesia
- Caution should be taken when Exelon Patch is used together with beta-blockers (medicines such as atenolol used to treat hypertension, angina, and other heart conditions). There may be additive effects such as bradycardia (slow heartbeat) that may result in syncope (fainting, loss of consciousness)

❗ Using Exelon Patch with food

Food or drink does not affect Exelon Patch because the active ingredient rivastigmine is absorbed into the bloodstream through the skin.

❗ Children and adolescents

Exelon Patch is not intended for use in children.

❗ Pregnancy and breast-feeding

- If you are pregnant the doctor must assess the benefits of Exelon Patch against the possible effects on the fetus**
- Tell the doctor if you are pregnant or planning to become pregnant
- Do not breast-feed during treatment with Exelon Patch**
- Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while you are breast-feeding

❗ Driving and using machines

You should consult the doctor to see whether your illness allows you to drive vehicles and operate machines safely and engage in any activity that requires alertness. Exelon Patch may cause dizziness and drowsiness, mainly at the start of treatment or when increasing the dose. If you feel dizzy or drowsy, avoid driving a vehicle or operating machinery or any activity that requires alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only.

The beginning of treatment and supervision of treatment will be carried out by a doctor experienced in the diagnosis and treatment of Alzheimer's dementia. Diagnosis should be carried out according to current guidelines. Similar to any treatment initiated in patients with dementia, therapy with rivastigmine should only be commenced if a caregiver is available to regularly administer and monitor the treatment.

How many Exelon patches to apply

Important: Only one patch should be worn at a time. You must remove the previous day's patch before applying a new one. Do not cut the patch into pieces.

How to start treatment

Your doctor will tell you which Exelon Patch is most suitable for you. Treatment usually starts with Exelon Patch 5 (4.6 mg/24 h). The usual daily dose is Exelon Patch 10 (9.5 mg/24 h). If well tolerated, your doctor may increase the dose to Exelon Patch 15 (13.3 mg/24 h). Only one patch should be worn at a time and the patch should be replaced by a new one after 24 hours.

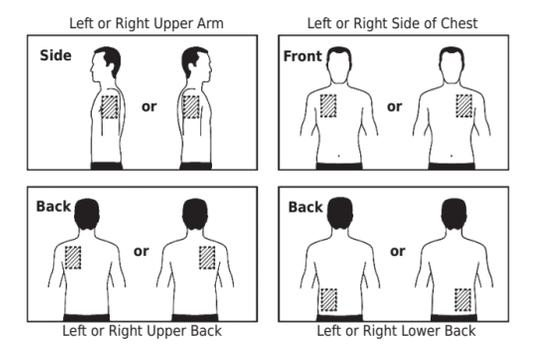
During the course of the treatment your doctor may adjust the dose to suit your individual needs.

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

Where to apply Exelon Patch

- Before you apply Exelon Patch, make sure that your skin is:
 - clean, dry and hairless
 - free of any powder, oil, moisturizer or lotion (that could keep the patch from sticking to your skin properly)
 - free of cuts, rashes and/or irritations
- Every 24 hours, gently remove an existing patch before putting on a new one. Having multiple patches on your body could expose it to an excessive amount of the medicine which could be dangerous.**
- Apply **ONLY ONE** patch per day to **ONLY ONE** of the following locations (shown in the figures below):
 - upper arm, left **or** right side, **or**
 - chest, left **or** right side (avoid applying to the breast), **or**
 - upper back area, left **or** right side, **or**
 - lower back area, left **or** right side

Avoid places where the patch can be rubbed and detached by tight clothing.

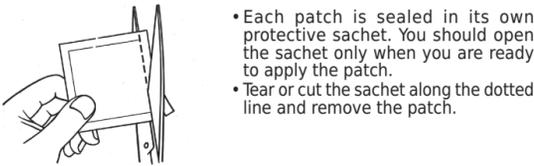


When changing the patch, you must remove the previous day's patch before you apply your new patch to a different area of skin (for example on the right side of your body one day, then on the left side the next day). Do not apply a new patch to that same area for at least one week.

How to apply Exelon Patch

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

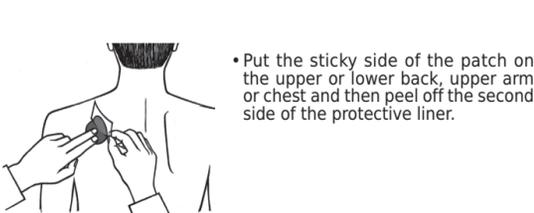
Every 24 hours, gently remove any existing patch before putting on a new one. Having multiple patches on your body could expose you to an excessive amount of this medicine which could be potentially dangerous.



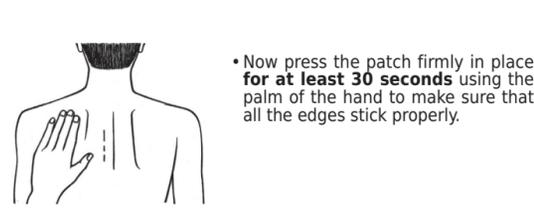
- Each patch is sealed in its own protective sachet. You should open the sachet only when you are ready to apply the patch.
- Tear or cut the sachet along the dotted line and remove the patch.



- A protective liner covers the adhesive 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 side of the protective liner.



- Now press the patch firmly in place **for at least 30 seconds** using the palm of the hand to make sure that all the edges stick properly.

- As a reminder, you may write (e.g. the day of the week) on the Exelon Patch with a thin ball point pen.

Exelon Patch should be worn continuously until it is time to replace it with a new patch. 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 on the patch.

How to remove Exelon Patch



Gently pull at one edge of the Exelon Patch to remove it whole from the skin.

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

How to dispose of Exelon Patch

After removing the patch, fold it in two with the adhesive side on the inside and press. Return the used patch to its original sachet and discard safely out of the reach and sight of children. Avoid contact of the fingers with the eyes and wash your hands with soap and water after removing the patch.

In case of contact with eyes or if the eyes become red after handling the patch, rinse immediately with plenty of water and seek medical help if symptoms do not resolve.

Can you wear the patch when bathing, swimming, or in the sun?

- Bathing, swimming, or showering should not affect the patch. When swimming, you can wear the patch under your bathing suit. Make sure the patch does not loosen during these activities.
- The patch should not be exposed to any external heat sources (excessive sunlight, saunas, solarium) for long periods of time.

What to do if the patch falls off

If the patch falls off, a new patch should be applied for the rest of the day, then replace the patch the next day at the same time as usual.

When and for how long to apply Exelon Patch

To benefit from your medicine you must apply a new patch every day. Applying Exelon Patch at the same time each day will help you remember when to use your medicine. Only wear one patch at a time and replace the patch with a new one after 24 hours.

Tell your caregiver that you are applying Exelon Patch. Also tell your caregiver if you have not applied Exelon Patch for more than three days.

If you have questions about the duration of treatment with Exelon, consult the doctor or pharmacist.

Tests and follow-up

The prescription of this medicine requires professional advice before treatment and periodic assessment of its therapeutic benefits. Likewise, your doctor will monitor your weight during treatment with this medicine.

If you apply more Exelon Patches than you should

If you accidentally apply more than one Exelon Patch, remove all the patches from your skin, and then inform your attending doctor that you have accidentally applied more than one Exelon Patch. You may require medical attention. Some people who have accidentally taken too much Exelon have experienced nausea, vomiting, diarrhea, high blood pressure and hallucinations. Slow heart beat and fainting may also occur.

If you forget to apply Exelon Patch

If you find you have forgotten to apply your 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 to make up for the one that you missed. Adhere to the treatment as recommended by the doctor.

If you stop taking Exelon Patch

Even if there is an improvement in your health, do not stop treatment with the medicine or change your dosage without consulting the doctor or pharmacist.

If you have not applied Exelon Patch for more than three days do not resume applying the patches without consulting with the attending doctor.

How can you contribute to the success of the treatment?

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them. If you have further questions regarding use of this 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 by the list of side effects. You may not suffer from any of them.

The frequency of side effects is higher at the start of treatment or when increasing the dose. In most cases the side effects will gradually disappear as your body gets used to the medicine. Side effects occur at the frequencies defined below:

Very common:	affects more than 1 patient in every 10 patients
Common:	affects between 1 and 10 patients in every 100 patients
Uncommon:	affects between 1 and 10 patients in every 1,000 patients
Rare:	affects between 1 and 10 patients in every 10,000 patients
Very rare:	affects less than 1 patient in every 10,000 patients
Unknown frequency:	cannot be estimated from the available data

Some side effects could be serious:

If you experience one or more of these effects, remove the Exelon Patch **and immediately inform the attending doctor:**

Common side effects (may affect between 1 and 10 in every 100 patients):
Depression.

Uncommon side effects (may affect between 1 and 10 in every 1,000 patients):

Losing too much fluid (dehydration), severe confusion, seeing, feeling or hearing things that are not there (hallucinations), loss of coordination, difficulty in speaking and signs of a brain disorder (stroke), fainting, irregular or fast or slow heart beat (heart rate problems), blood in stools or in vomit (gastric ulcer and gastrointestinal hemorrhage).

Very rare side effects (may affect less than 1 in every 10,000 patients):

Severe upper stomach pain, often with nausea and vomiting (inflammation of the pancreas), fits or convulsions.

Side effects of unknown frequency:

Yellow skin, yellowing of the whites of the eyes, abnormally dark 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).

Other side effects:

If one or more of these effects affects you severely, **consult the doctor:**

Very common side effects (may affect more than 1 in every 10 patients):
Nausea (gastrointestinal reactions).

Common side effects (may affect between 1 and 10 in every 100 patients):

Loss of appetite, anxiety, difficulty sleeping, dizziness, headache, vomiting, diarrhea, stomach discomfort after meals, stomach pain, inability to adequately retain urine (urinary incontinence), redness, itching, irritation, swelling at the application site (skin reactions at the application site), tiredness, weakness, weight loss, urinary tract infection.

Uncommon side effects (may affect between 1-10 in every 1,000 patients):

Agitation, aggression, drowsiness (common in Chinese patients), unusually high level of activity, restlessness (hyperactivity), sweating, general feeling of being unwell.

Rare side effects (may affect between 1-10 in every 10,000 patients):

High blood pressure, rash and itching or skin reddening upon contact with the patch (very common in Japanese patients), itching, rash, skin reddening, blisters, inflammatory rash, falls.

Very rare side effects (may affect less than 1 in every 10,000 patients):

Muscle stiffness, difficulty in carrying out movements (worsening of Parkinson's disease).

Side effects of unknown frequency:

Restlessness, changes in the results of liver function tests, trembling.

Additional side effects which have been reported with Exelon capsules:

Common side effects (may affect between 1 and 10 in every 100 patients):
Confusion.

Rare side effects (may affect between 1 and 10 in every 10,000 patients):

Chest pain, crushing chest pain (heart attack), ulcer on the intestine.

Very rare side effects (may affect less than 1 in every 10,000 patients):

Severe vomiting that can lead to a rupture of the esophagus.

Additional side effects reported for Exelon capsules in patients with dementia associated with Parkinson's disease: too much saliva (common).

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

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 of children and/or infants in order to avoid poisoning.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month. Store below 25°C.

Do not use if the package is damaged or if there are signs of opening.

Keep out of the reach and sight of children.

How to dispose of Exelon Patch:

See section 3 'How should you use the medicine?'

6. FURTHER INFORMATION

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

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

What the medicine looks like and the contents of the package

Each patch is a thin, matrix-type transdermal patch consisting of 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.

It is possible that not all package sizes are marketed.

Registration holder and address:

Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

Manufacturer and address:

LTS Lohmann Therapie-Systeme AG, Andernach, Germany
For Novartis Pharma AG, Basel, Switzerland.

This leaflet was checked and approved by the Ministry of Health in August 2014.

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