

# EXELON PATCH<sup>®</sup>

Consumer Medication Information Leaflet (RiMUP)

Rivastigmine

4.6 mg/24 h transdermal patch (Exelon<sup>®</sup> Patch 5)

9.5 mg/24 h transdermal patch (Exelon<sup>®</sup> Patch 10)

13.3 mg/24 h transdermal patch (Exelon<sup>®</sup> Patch 15)

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## What is in this leaflet

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

## What Exelon Patch is used for

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

## How Exelon Patch works

Exelon belongs to a class of substances called cholinesterase inhibitors. The active substance of Exelon is rivastigmine. In patients with Alzheimer's dementia or Parkinson's disease 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). 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 or Parkinson's disease dementia.

## Before you apply Exelon Patch

### - When you must not use it

Do not apply Exelon Patch

- If you know that you are allergic (hypersensitive) to rivastigmine (the active substance in Exelon Patch) 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 you have had a skin reaction which has spread beyond the patch size, if there was a more intense local reaction (such as blisters, increasing skin inflammation, swelling) and if it did not improve within 48 hours after removal of the transdermal patch.

If any of these apply to you, **do not apply Exelon Patch 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.

Read the following information before you apply Exelon Patch.

### - 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 Patch should not be given together with other medicines with similar effects (cholinomimetic agents) or with anticholinergic medicines (such as medicines used to relieve stomach cramps or spasms or to prevent travel sickness). Exelon Patch should not be given 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 have to undergo surgery whilst using Exelon Patch, you should inform your doctor because Exelon Patch may exaggerate the effects of some muscle relaxants during anesthesia.

Caution when Exelon Patch is given 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).

Caution when Exelon is taken together with medicinal products 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 Patch with food and drink

Food or drink does not affect Exelon Patch because rivastigmine enters your bloodstream through your skin.

### Older patients (65 years of age or above)

Exelon Patch can be used by elderly patients over the age of 65.

### Children and adolescents (below 18 years of age)

The use of Exelon Patch in children and adolescents is not recommended.

### Pregnancy and breast-feeding

If you are pregnant, the benefits of Exelon Patch 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 Patch. Ask your doctor, pharmacist or healthcare provider for advice before taking any medicine while you are breast-feeding.

**How to use Exelon Patch**

Always apply this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacists, or healthcare provider if you are not sure. Do not exceed the recommended dose prescribed by your doctor.

- How many Exelon Patches to apply

**IMPORTANT:** Only one patch should be worn at a time. You must remove the previous day's Exelon 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 more 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 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 before you have talked to your doctor.

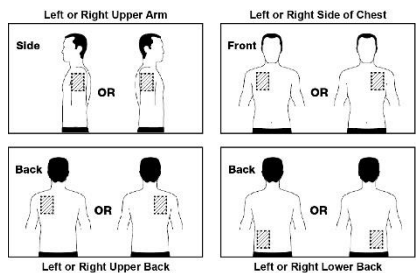
- Where to apply Exelon Patch

- Before you apply Exelon Patch, make sure that your skin is:
  - clean, dry and hairless
  - free of any powder, oil, moisturiser, or lotion (that could keep the patch from sticking to your skin properly)
  - free of cuts, rashes and/or irritations.
- **Every 24 hours, please gently remove any existing Exelon 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.**

- 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, or
  - upper back, left or right side, or
  - lower back, left or right side.

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

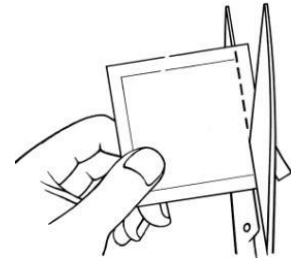


When changing your patch, you must remove the previous day's patch before you apply your new patch to a different area of skin (for example on the right side of your body one day, then on the left side the next day). However, consecutive patches can be applied to the same general anatomic area (e.g., if the first patch is applied on right upper arm, the next patch can be applied to left upper arm or to another spot on the right upper arm). Do not apply a new patch to that same skin spot for at least 14 days.

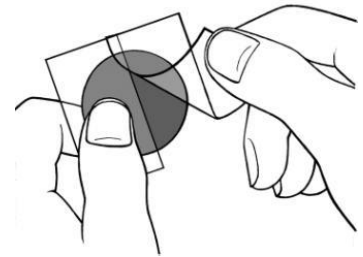
- How to apply Exelon Patch

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 a patch until just before you apply it.

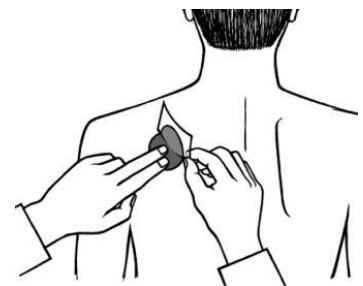
- Each patch is sealed in its own protective sachet. You should only open the sachet when you are ready to apply the patch.
- Tear or cut the sachet at the notch and remove the patch.



- 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.



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

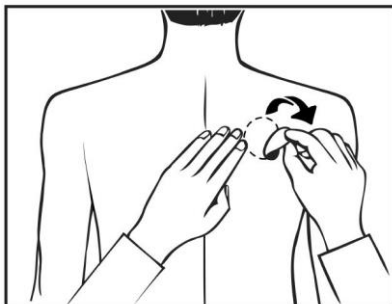


- If it helps you, you may write (e.g. the day of the week) on the

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 ones 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 completely from the skin.

In case the adhesive residue is left over on your skin, gently soak 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.

- What to do if Exelon 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. Taking Exelon at the same time each day will help you remember when to take your medicine. Only wear one Exelon Patch at a time and replace the patch by a new one after 24 hours. Tell your caregiver that you are applying Exelon Patch. Also tell your caregiver if you have not been applying Exelon Patch for more than three days.

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 use Exelon Patch, talk to your doctor, your pharmacist or healthcare provider.

- 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 Exelon patches to make up for the one that you missed.

- If you apply more Exelon Patches than you should (overdose)

If you accidentally apply more than one Exelon Patch, remove all the Exelon patches from your skin, then inform your 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 (feeling sick), vomiting (being sick), diarrhea, high blood pressure and hallucinations. Slow heart-beat and fainting may also occur.

**While you are using Exelon Patch**

- Things you must do

Warnings and precautions

- If you experience gastrointestinal reactions such as nausea (feeling sick), vomiting (being sick) and diarrhea. You may become dehydrated (losing too much fluid) if vomiting or diarrhea are prolonged,
- If you have, or have ever had heart conditions such as an 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 an active stomach ulcer,
- 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 a severe respiratory disease,

- If you suffer from trembling,
- If you have a low body weight (less than 50 kg),
- If you have impaired liver function.

If any of these apply to you, your doctor may 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 three days do not apply the next patch until you have talked to your doctor.

- Things you must not do

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

If you have not applied Exelon Patch for more than three days do not apply the next patch until you have talked to your doctor.

- Things to be careful of

- Bathing, swimming, or showering should not affect the patch. When swimming, you can wear the patch under your swimming costume. 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.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Exelon Patch may cause dizziness and drowsiness, mainly at the start of treatment or when increasing the dose. Therefore, you should wait to know what effects Exelon Patch 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, patients using Exelon Patch 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. In most cases side effects will gradually disappear as your body gets used to the medicine.

Some side effects could be serious.

If you experience any serious side effects, remove the Exelon Patch, and tell your doctor immediately.

**Common** (may affect up to 1 in every 10 people): depression.

**Uncommon** (may affect up to 1 in every 100 people): dehydration (losing too much fluid), severe confusion, hallucinations (seeing, feeling or hearing things that are not there), stroke (loss of coordination, difficulty in speaking and signs of brain disorder), fainting, problems with heart rhythm (irregular or fast or slow heart beat), gastric ulcer and gastrointestinal haemorrhage (blood in stools or when vomiting).

**Very rare** (may affect up to 1 in every 10,000 patients): inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting), fits or convulsions.

**Frequency not known:** liver disorders (yellow skin, yellowing of the whites of eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite), skin inflammation, blisters or swelling of the skin that are increasing and spreading, stiff limbs, trembling hands (extrapyramidal symptoms).

Other possible side effects

**Very common** (may affect more than 1 in 10 people): gastrointestinal reactions such as nausea (feeling sick).

**Common** (may affect up to 1 in every 10 people): loss of appetite, anxiety, difficulty in sleeping, dizziness, headache, vomiting, diarrhoea, stomach discomfort after meal, stomach pain, urinary incontinence (inability to retain adequately urine), skins reactions at the application site (redness, itching, irritation, swelling), tiredness, weakness, weight loss, urinary tract infection (infection involving the part of the body producing urine).

**Uncommon** (may affect up to 1 in every 100 people): agitation, aggression, drowsiness (common in Chinese patients), hyperactivity (unusual high level of activity, restlessness), sweating, general feeling of being unwell.

**Rare** (may affect up to 1 in every 1,000 people): high blood pressure, rash and itching on contact with the patch (very common in Japanese patients), itching, rash, skin reddening, blister, skin inflammation with rash, fall.

**Very rare** (may affect up to 1 in every 10,000 people): worsening of Parkinson's disease symptoms (such as muscle stiffness, difficulty in carrying out movements).

**Frequency not known:** restlessness, changes in the results of liver function tests, trembling, nightmares

Additional information for patients with Parkinson's disease

Some side effects are more frequent in patients with dementia associated with Parkinson's disease: fall (very common); agitation, aggression, hallucination, drowsiness, muscle stiffness, high blood pressure and dehydration (losing too much fluid) (common).

Some additional side effects observed with Exelon Patch in patients with dementia associated with Parkinson's disease are: trembling, development of symptoms similar to worsening of Parkinson's disease (abnormally decreased muscular movement, abnormally slow movements,

uncontrollable movement of mouth, tongue and limbs) and abnormal way of walking (common).

If any of these affects you severely, tell your doctor.

Additional side effects which have been reported with Exelon capsules

**Common** (may affect up to 1 in every 10 people): confusion

**Rare** (may affect up to 1 in every 1,000 people): chest pain, heart attack (crushing chest pain), ulcer in the intestine.

**Very rare** (may affect up to 1 in every 10,000 patients): severe vomiting that can lead to a rupture of the oesophagus.

Some additional side effects observed with Exelon capsules in patients with dementia associated with Parkinson's disease are: too much saliva (common).

In addition, you should contact your doctor or pharmacist 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](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Exelon Patch

- Do not use Exelon Patch after the expiry date shown on the box and sachet.
- Do not store Exelon Patch above 30°C.
- Do not use any Exelon Patch that is damaged or shows signs of tampering.
- Keep Exelon Patch out of the reach and sight of children.

- Disposal

After the patch has been removed, fold it in half with the adhesive sides on the inside and press them together. Return the used patch to its original sachet and discard safely out of the reach and sight of children. Wash

your hands with soap and water after removing the patch.

Damansara Uptown,  
47400 Petaling Jaya, Selangor

**Product Description**

*- What it looks like*

Each patch is a thin, matrix-type transdermal patch consisting of three layers. The outside of the backing layer is beige and labelled respectively with:

- for Exelon Patch 5: “AMCX”,
- for Exelon Patch 10: “BHDI”,
- for Exelon Patch 15: “CNFU”

*- Ingredients:*

Active Ingredient:

Exelon Patch 5: each 5 cm<sup>2</sup> transdermal patch contains 9 mg rivastigmine. The release rate is 4.6 mg/24h.

Exelon Patch 10: each 10 cm<sup>2</sup> transdermal patch contains 18 mg rivastigmine. The release rate is 9.5 mg/24h.

Exelon Patch 15: each 15 cm<sup>2</sup> transdermal patch contains 27 mg rivastigmine. The release rate is 13.3 mg/24h.

Inactive Ingredients: acrylic pressure sensitive adhesive, silicone pressure sensitive adhesive, poly (butylmethacrylate, methyl-methacrylate), polyethylene terephthalate (backing film), fluoropolymer-coated polyethylene terephthalate (release liner), silicone oil and vitamin E

*- MAL Numbers*

- Exelon Patch 5  
MAL20081794ACRZ
- Exelon Patch 10  
MAL20081795ACRZ
- Exelon Patch 15  
MAL14075044ACRZ

**Manufacturer**

LTS Lohmann Therapie-Systeme  
AG., Lohmannstrasse 2, 56626  
Andernach, Germany

**Product Registration Holder**

Novartis Corporation (Malaysia) Sdn  
Bhd  
Level 18, Imazium,  
No. 8, Jalan SS21/37,

**Date of revision**

19-Jan-2023

Information issued:

12-Dec-2022

**Serial Number**

NPRA (R1/3) 15022023/047