

PACKAGE LEAFLET: INFORMATION FOR THE USER

Exelon 4.6 mg/24 h transdermal patch
Exelon 9.5 mg/24 h transdermal patch
rivastigmine

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Exelon is and what it is used for
2. Before you use Exelon
3. How to use Exelon
4. Possible side effects
5. How to store Exelon
6. Further information

1. WHAT EXELON IS AND WHAT IT IS USED FOR

The active substance of Exelon is rivastigmine.

Rivastigmine belongs to a class of substances called cholinesterase inhibitors. Exelon is used for the treatment of memory disorders in patients with Alzheimer's disease.

2. BEFORE YOU USE EXELON

Do not use Exelon

- if you are allergic (hypersensitive) to rivastigmine (the active substance in Exelon) or to any of the other ingredients listed in section 6 of this leaflet.
- if you have ever had an allergic reaction to a similar type of medicine.

If this applies to you, tell your doctor and do not apply Exelon transdermal patches.

Take special care with Exelon

- if you have, or have ever had, an irregular heartbeat.
- if you have, or have ever had, a stomach ulcer.
- if you have, or have ever had, difficulties in passing urine.
- if you have, or have ever had, seizures.
- 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.
- 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.

If you have not applied a patch for several days, do not apply the next one before you have talked to your doctor.

The use of Exelon in children and adolescents (age below 18 years) is not recommended.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Exelon might interfere with anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness).

If you have to undergo surgery whilst using Exelon transdermal patches, tell your doctor that you are using them because they may exaggerate the effects of some muscle relaxants during anaesthesia.

Using Exelon with food and drink

Food or drink do not affect the use of Exelon transdermal patches because rivastigmine enters the bloodstream through the skin.

Pregnancy and breast feeding

Tell your doctor if you are pregnant or planning to become pregnant. If you are pregnant, the benefits of using Exelon transdermal patches must be assessed against the possible effects on your unborn child.

You should not breast-feed during treatment with Exelon transdermal patches.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Exelon transdermal patches may cause fainting or severe confusion. If you feel faint or confused do not drive, use machines or perform any other tasks that require your attention.

3. HOW TO USE EXELON

Always use Exelon transdermal patches exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

IMPORTANT: Only wear one Exelon patch 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 transdermal patch is most suitable for you.

- Treatment usually starts with Exelon 4.6 mg/24 h.
- The usual daily dose is Exelon 9.5 mg/24 h.
- Only one transdermal patch should be worn at a time and the transdermal patch should be replaced by a new one after 24 hours.

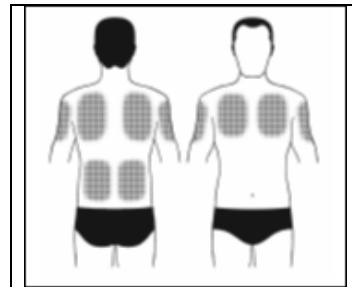
During the course of the treatment your doctor may adjust the dose to suit your individual needs.

If you have not applied a patch for several days, talk to your doctor before applying another one.

Where to apply your Exelon transdermal patch

- Before you apply a 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.

- Carefully 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.
- Apply **only one** patch per day to **only one** of the following locations: the upper **or** lower back, upper arm **or** chest (avoid breast). Avoid places where the patch can be rubbed off by tight clothing.



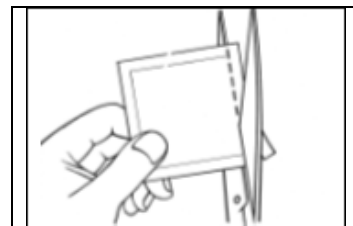
The grey areas are for illustrative purposes. Apply **only one** patch per day to **only one** of the locations in grey.

When changing the patch, apply the new one to a different location of skin each time (for example on the right side of your body one day, then on the left side the next day, and on your upper body one day, then on your lower body the next day). Do not apply a new patch to that same location of skin twice within 14 days.

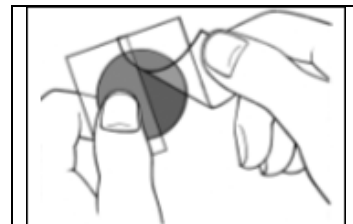
How to apply your Exelon transdermal patch

Exelon patches are thin, opaque, plastic patches that stick 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. 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 side of the protective liner.



- Then press the patch firmly in place with 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.

The patch should be worn 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 ones that are most comfortable for you and where clothing will not rub on the patch.

How to remove your Exelon transdermal patch

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

How to dispose of your Exelon transdermal patch

After removing a patch, fold it in half with the sticky sides on the inside and press them together. Return the used patch to its sachet and dispose of it in such a way that children cannot handle it. Do not touch your eyes with your fingers and wash your hands with soap and water after removing the patch.

If your community burns domestic rubbish, you can dispose of the patch with your domestic rubbish. Otherwise, return used patches to a pharmacy, preferably in the original packaging.

Can you wear your Exelon transdermal patch when you are bathing, swimming, or in the sun?

- Bathing, swimming or showering should not affect the patch. Make sure 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 a patch falls off

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

When and for how long to apply your Exelon transdermal patch

To benefit from treatment, you must apply a new patch every day, preferably at the same time of day.

If you use more Exelon than you should

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

If you forget to use Exelon

If you find you have forgotten to apply a patch, apply one 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.

If you stop using Exelon

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

If you have not applied an Exelon patch for several days, do not apply the next one until you have talked to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Exelon transdermal patches can cause side effects, although not everybody gets them.

You may see side effects more frequently when you start your medicine or increase to a higher dose. In most cases side effects will gradually disappear as your body gets used to the medicine. Stomach (gastrointestinal) reactions such as feeling sick (nausea) and being sick (vomiting) are common side effects (less than 1 in 10 patients but more than 1 in 100 patients). The other common side effects are: diarrhoea, heartburn, stomach pain, loss of appetite, weight loss, urinary tract infection, headache, weakness, tiredness, anxiety, depression, fainting, rash, skin reactions at the application site (redness, itching, irritation, swelling), severe confusion and fever.

Some side effects could become serious:

Uncommon side effects (less than 1 in 100 patients but more than 1 in 1,000 patients): problems with heart rhythm (slow heart beat), hallucination and gastric ulcer; very rare (less than 1 in 10,000 patients): stiff limbs and trembling hands.

Additional side effects which have been reported during post-marketing with Exelon transdermal patches: high blood pressure, application site allergic reaction (e.g. blisters, skin inflammation), fast heart beat, irregular heart beat, inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting), fall, convulsion, worsening of Parkinson's disease (tremor, stiffness, shuffling).

If you experience any of these, remove the patch and tell your doctor straight away.

Additional side effects which have been reported with Exelon capsules or oral solution are:

Very common (more than 1 in 10 patients): dizziness.

Common (less than 1 in 10 patients but more than 1 in 100 patients): agitation, drowsiness, generally feeling unwell, trembling, confusion and increased sweating.

Uncommon (less than 1 in 100 patients but more than 1 in 1,000 patients): difficulty in sleeping, changes in liver function tests and accidental falls.

Rare (less than 1 in 1,000 patients but more than 1 in 10,000 patients): convulsions, ulcer in the intestine and chest pain (probably caused by coronary spasm).

Very rare (less than 1 in 10,000 patients): irregular heart rate (e.g. fast heart rate), high blood pressure, inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting), gastrointestinal haemorrhage (blood in stools or when vomiting), hallucinations.

There have also been reports about severe vomiting that can lead to a rupture of the oesophagus.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EXELON

- Keep out of the reach and sight of children.
- Do not use Exelon after the expiry date, which is stated on the carton and sachet. The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Keep the transdermal patch in the sachet until use.
- Do not use any patch that is damaged or shows signs of tampering.

6. FURTHER INFORMATION

What Exelon contains

- The active substance is rivastigmine.
 - Exelon 4.6 mg/24 h transdermal patches: Each patch releases 4.6 mg of rivastigmine per 24 hours is 5 cm² and contains 9 mg of rivastigmine.
 - Exelon 9.5 mg/24 h transdermal patches: Each patch releases 9.5 mg of rivastigmine per 24 hours is 10 cm² and contains 18 mg of rivastigmine.
- The other ingredients are: polyethylene terephthalate film lacquered, alpha-tocopherol, poly(butylmethacrylate, methyl-methacrylate), acrylic copolymer, silicone oil, dimethicone, polyester film fluoropolymer-coated.

What Exelon looks like and contents of the pack

Each transdermal patch is a thin patch consisting of three layers. The outer layer is beige and labelled with the following:

- “Exelon”, “4.6 mg/24 h” and “AMCX”,
- “Exelon”, “9.5 mg/24 h” and “BHDI”.

One transdermal patch is sealed in one sachet. The patches are available in packs containing 7 or 30 sachets and in multipacks containing 60 (2x 30) or 90 (3x 30) sachets. Not all pack sizes may be marketed in your country.

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Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>