

17.8 FDA-Approved Patient Labeling

What is Exelon Patch and what it is used for?

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

Before you apply Exelon Patch:

Carefully follow all instructions given to you by your doctor, even if they differ from the information contained in this leaflet.

Read the following information before you apply Exelon Patch.

Do not apply Exelon Patch in the following cases:

If you know that you are allergic (hypersensitive) to rivastigmine (the active substance in Exelon Patch) or to any of the other ingredients of Exelon Patch [see *Description (11)*].

If you have ever had an allergic reaction to a similar type of medicine.

If this applies to you, tell your doctor without applying Exelon Patch.

Take special care with Exelon Patch if:

- You have, or ever had an irregular heartbeat.
- You have, or ever had an active stomach ulcer.
- You have, or ever had difficulties in passing urine.
- You have, or ever had seizures.
- You have, or ever had asthma or a severe respiratory disease.
- You suffer from trembling.
- You have a low body weight.
- 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 been applying Exelon Patch for several days do not apply the next patch until you have talked to your doctor.

Exelon Patch with food and drink:

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

Exelon Patch and older people:

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

Exelon Patch and children:

The use of Exelon Patch in children is not recommended.

Pregnant women:

Tell your doctor if you are pregnant or planning to become pregnant. In the event of pregnancy, the benefits of Exelon Patch must be assessed against the possible effects on your unborn child. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Breast-feeding mothers:

You should not breast-feed during treatment with Exelon Patch. Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

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. If you feel dizzy or drowsy, do not drive, use machines or perform any other tasks that require your attention.

Taking other medicines:

Tell your doctor or pharmacist about any other medicines you are taking or have recently taken, including any you get without a prescription.

Exelon Patch should not be given together with other medicines with similar effects (cholinomimetic agents) or with anticholinergic medicines.

If you need to have surgery while using Exelon Patch, you should inform your doctor because Exelon Patch may exaggerate the effects of some muscle relaxants during anesthesia.

How to use Exelon Patch:

Follow all instructions given to you by your doctor carefully, even if they differ from the ones given in this leaflet.

This medicine must not be given to children.

Do not eat Exelon Patch.

You must remove Exelon Patch from the previous day *before* applying a new one. Do not cut the patch into pieces.

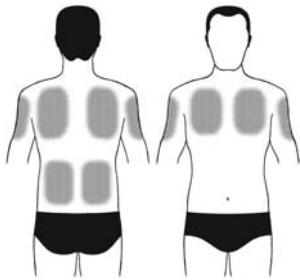
How to start treatment:

Your doctor will tell you which Exelon Patch is suitable for you. Treatment usually starts with Exelon Patch 4.6 mg/24 hours, and after several weeks many patients move to Exelon Patch 9.5 mg/24 hours as the usual daily dose. Apply the correct dose as directed by your doctor. The patch should be replaced by a new one after 24 hours.

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

If you have not been applying Exelon Patch for several days, do not apply the next patch before you have talked to your doctor.

Where to apply Exelon Patch:



Apply the patch to the upper **or** lower back if it is likely that the patient will remove it. If this is not a concern, the patch can be applied **instead** to the upper arm **or** chest. Avoid places where the patch can be rubbed off by tight clothing.

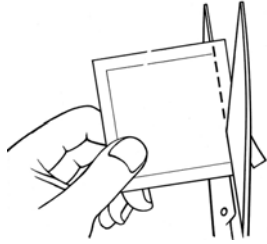
Before you apply Exelon Patch, make sure that your skin is:

- 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

When changing the patch, apply a new patch to a different spot of skin (for example on the right side of the body one day, then on the left side the next day). Do not apply a new patch to that same spot for at least 14 days. Apply the correct dose as directed by your doctor. The patch should be replaced by a new one after 24 hours.

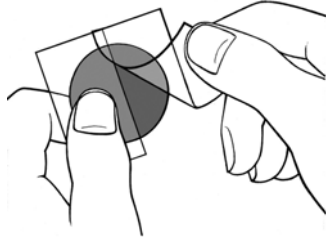
How to apply Exelon Patch:

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



Cut the pouch along the dotted line and remove the patch.

The patch should not be cut or folded sharply.



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.



Press the patch firmly in place with the hand to make sure that the edges stick well.

You may write (e.g., the day of the week) on 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. Avoid placing the patch where it could be rubbed off by clothing.

How to remove Exelon Patch:

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

How to dispose of Exelon Patch:

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 pouch and discard safely out of the reach and sight of children and pets as there may be medicine left over in the patch. Wash your hands with soap and water after removing the patch.

Can Exelon Patch be worn 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 swimsuit. Make sure the patch does not loosen during these activities.

The patch should not be exposed to any external heat sources (excessive sunlight, saunas, solariums) for long periods of time.

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 and then replaced the next day at the same time as usual.

When and how long to apply Exelon Patch:

To benefit from your medicine you must apply a new patch every day.

Tell your caregiver that you are applying Exelon Patch. Also tell your caregiver if you have not been applying Exelon Patch for several days.

What to do if you apply more Exelon patches than you should:

If you accidentally apply more Exelon patches than you should, remove all Exelon patches from your skin, and then inform your doctor that you have accidentally applied more Exelon patches than you should have. 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 heartbeat and fainting may also occur.

If you forget to apply Exelon Patch:

If you have forgotten to apply 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 have not been applying Exelon Patch for several days do not apply the next patch before you have talked to your doctor.

Possible side effects:

Like all medicines, Exelon Patch can cause 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 becomes used to the medicine. Gastrointestinal reactions such as nausea (feeling sick) and vomiting (being sick) are the most common side effects. The other common side effects are: loss of appetite, anxiety, difficulty sleeping, dizziness, headache, diarrhea, stomach discomfort after meals, stomach pain, skin reactions at the application site (redness, itching, irritation, swelling), fatigue, weakness, and weight loss.

Some side effects could become serious:

Common: depression.

Uncommon: severe confusion, hallucinations, vascular accident involving the brain (loss of coordination, difficulty in speaking or breathing and signs of brain disorder), fainting, problems with heart rhythm (irregular or fast or slow heartbeat), gastric ulcer and gastrointestinal hemorrhage (blood in stools or when vomiting).

If you experience any of these, remove Exelon Patch *and tell your doctor right away.*

Other side effects:

Uncommon: agitation, drowsiness, sweating and a general feeling of being unwell.

If any of these affect you severely, *tell your doctor.*

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

Common: confusion and trembling.

Uncommon: changes in liver function tests and accidental falls.

Rare: convulsions, chest pain, duodenal ulcer and rash.

Very rare: urinary tract infection, high blood pressure, inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting) and severe vomiting that can lead to a rupture of the esophagus.

In addition, you should contact your doctor or pharmacist if you experience any other possible side effects not mentioned in this leaflet.

How to store Exelon Patch:

Do not use Exelon Patch after the expiration date shown on the carton and pouch.

Store at room temperature, 59-86°F (15-30°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 and pets.

Distributed by:

Novartis Pharmaceuticals Corporation

East Hanover, New Jersey 07936

REV: JANUARY 2009

T2009-09

©Novartis