

Patient Information
EXELON® (ECS-`el-on) PATCH
(rivastigmine transdermal system)

What is the most important information I should know about EXELON PATCH?

EXELON PATCH is for skin use only.

What is EXELON PATCH?

EXELON PATCH is a prescription medicine used to treat:

- Mild, moderate, and severe memory problems (dementia) associated with Alzheimer's disease.
- Mild-to-moderate memory problems (dementia) associated with Parkinson's disease (PD).

Based on clinical trials conducted over 6 to 12 months, EXELON PATCH was shown to help with cognition which includes (memory, understanding communication, and reasoning) and with doing daily tasks. EXELON PATCH does not work the same in all people. Some people treated with EXELON PATCH may:

- Seem much better
- Get better in small ways or stay the same
- Get worse but slower than expected
- Not change and then get worse as expected

Some patients will not benefit from treatment with EXELON Patch. EXELON PATCH does not cure Alzheimer's disease. All patients with Alzheimer's disease get worse over time.

EXELON PATCH comes as a transdermal system that delivers rivastigmine (the medicine in EXELON PATCH) through the skin.

It is not known if EXELON PATCH is safe or effective in children under 18 years of age.

Who should not use EXELON PATCH?

Do not use EXELON PATCH if you:

- are allergic to rivastigmine, carbamate derivatives, or any of the ingredients in EXELON PATCH. See the end of this leaflet for a complete list of ingredients in EXELON PATCH.
- have had a skin reaction that:
 - spread beyond the EXELON PATCH size
 - had blisters, increased skin redness, or swelling
 - did not get better within 48 hours after you removed the EXELON PATCH

Ask your healthcare provider if you are not sure if you should use EXELON PATCH.

What should I tell my healthcare provider before using EXELON PATCH?

Before you use EXELON PATCH, tell your healthcare provider if you:

- have or have had a stomach ulcer
- are planning to have surgery
- have or have had problems with your heart
- have problems passing urine
- have or have had seizures
- have problems with movement (tremors)
- have asthma or breathing problems
- have a loss of appetite or are losing weight
- have had a skin reaction to rivastigmine (the medicine in EXELON PATCH) in the past
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if the medicine in EXELON PATCH will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if the medicine in EXELON PATCH passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take EXELON PATCH.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take:

- a medicine used to treat inflammation [nonsteroidal anti-inflammatory drugs (NSAIDs)]
- other medicines used to treat Alzheimer's or Parkinson's disease
- an anticholinergic medicine, such as an allergy or cold medicine, a medicine to treat bladder or bowel spasms, or certain asthma medicines, or certain medicines to prevent motion or travel sickness
- metoclopramide, a drug given to relieve symptoms of nausea, gastroesophageal reflux disease (GERD), or nausea and vomiting after surgery or chemotherapy treatment
- If you are undergoing surgery while using EXELON PATCH, inform your doctor because EXELON PATCH may exaggerate the effects of anesthesia, or the effects of a beta-blocker, a type of medicine given for high blood pressure, heart disease, and other medical conditions

Ask your healthcare provider if you are not sure if your medicine is one listed above.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I use EXELON PATCH?

- Use EXELON PATCH exactly as your healthcare provider tells you to use it.
- EXELON PATCH comes in 3 different dosage strengths.
- Your healthcare provider may change your dose as needed.
- Wear only 1 EXELON PATCH at a time.
- EXELON Patch is for skin use only.
- Only apply EXELON PATCH to healthy skin that is clean, dry, hairless, and free of redness, irritation, burns or cuts.
- Avoid applying EXELON PATCH to areas on your body that will be rubbed against tight clothing.
- Do not apply EXELON PATCH to skin that has cream, lotion, or powder on it.
- Change your EXELON PATCH every 24 hours at the same time of day. You may write the date and time you put on the EXELON PATCH with a ballpoint pen before applying the patch to help you remember when to remove it.
- Change your application site every day to avoid skin irritation. You can use the same area, but do not use the exact same spot for at least 14 days after your last application.
- Check to see if the EXELON PATCH has become loose when you are bathing, swimming, or showering.
- EXELON PATCH is designed to deliver medication during the time it is worn. If your EXELON PATCH falls off before its usual replacement time, put on a new EXELON PATCH right away. Replace the new patch the next day at the same time as usual. Do not use overlays, bandages, or tape to secure an EXELON PATCH that has become loose or try to reapply an EXELON PATCH that has fallen off.
- If you miss a dose or forget to change your EXELON PATCH, apply your next EXELON PATCH as soon as you remember. Do not apply 2 EXELON PATCHes to make up for the missed dose.
- If you miss more than 3 doses of applying EXELON PATCH, call your healthcare provider before putting on a new EXELON PATCH. You may need to restart EXELON PATCH at a lower dose.
- Always remove the old EXELON PATCH from the previous day before you apply a new one.
- **Having more than 1 EXELON PATCH on your body at the same time can cause you to get too much medicine.** If you accidentally use more than 1 EXELON PATCH at a time, call your healthcare provider right away. If you are unable to reach your healthcare provider, call your local Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while using EXELON PATCH?

- Do not touch your eyes after you touch the EXELON PATCH. In case of accidental contact with your eyes or if your eyes become red after handling the patch, rinse immediately with plenty of water and seek medical advice if symptoms do not resolve.
- EXELON PATCH can cause drowsiness, dizziness, weakness, or fainting. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EXELON PATCH affects you.
- Avoid exposure to heat sources, such as excessive sunlight, saunas, or sunrooms for long periods of time.

What are the possible side effects of EXELON PATCH?

EXELON PATCH may cause serious side effects, including:

- **Medication overdose.** Hospitalization and rarely death may happen when people accidentally wear more than 1 patch at the same time. It is important that the old EXELON PATCH be removed before you apply a new one. Do not wear more than 1 EXELON PATCH at a time.
- **Stomach or bowel (intestinal) problems, including:**
 - nausea
 - vomiting
 - diarrhea
 - dehydration
 - loss of appetite
 - weight loss
 - bleeding in your stomach (ulcers)
- **Skin reactions.** Some people have had a serious skin reaction called allergic contact dermatitis (ACD) when using EXELON PATCH. Stop using EXELON PATCH and call your healthcare provider right away if you experience reactions that spread beyond the patch size, are intense in nature and do not improve within 48 hours after the patch is removed. Symptoms of ACD may be intense and include:
 - itching, redness, swelling, warmth or tenderness of the skin
 - peeling or blistering of the skin that may ooze, drain or crust over
- **Heart problems**
- **Seizures**
- **Problems with movement (tremors)**

The most common side effects of EXELON PATCH include:

- depression
- headache
- anxiety
- dizziness

- stomach pain
- urinary tract infections
- muscle weakness
- tiredness
- trouble sleeping

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of EXELON PATCH. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store EXELON PATCH?

- Store EXELON PATCH between 68°F to 77°F (20°C to 25°C).
- Keep EXELON PATCH in the sealed pouch until ready to use.

Keep EXELON PATCH and all medicines out of the reach of children.

General information about the safe and effective use of EXELON PATCH.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use EXELON PATCH for a condition for which it was not prescribed. Do not give EXELON PATCH to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about EXELON PATCH. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about EXELON PATCH that is written for health professionals.

For more information, go to www.EXELONPATCH.com or call 1-888-669-6682.

What are the ingredients of EXELON PATCH?

Active ingredient: rivastigmine

Excipients include: acrylic copolymer, poly (butylmethacrylate, methylmethacrylate), silicone adhesive applied to a flexible polymer backing film, silicone oil, and vitamin E.

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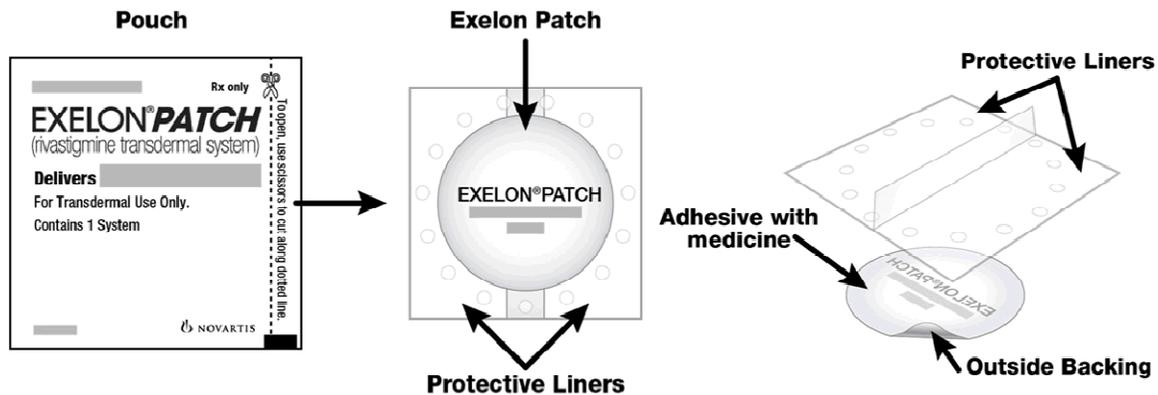
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Instructions for Use
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(rivastigmine transdermal system)

You will need the following supplies (See Figure A):

EXELON PATCH is supplied in cartons containing 30 patches (See Figure A)

Figure A



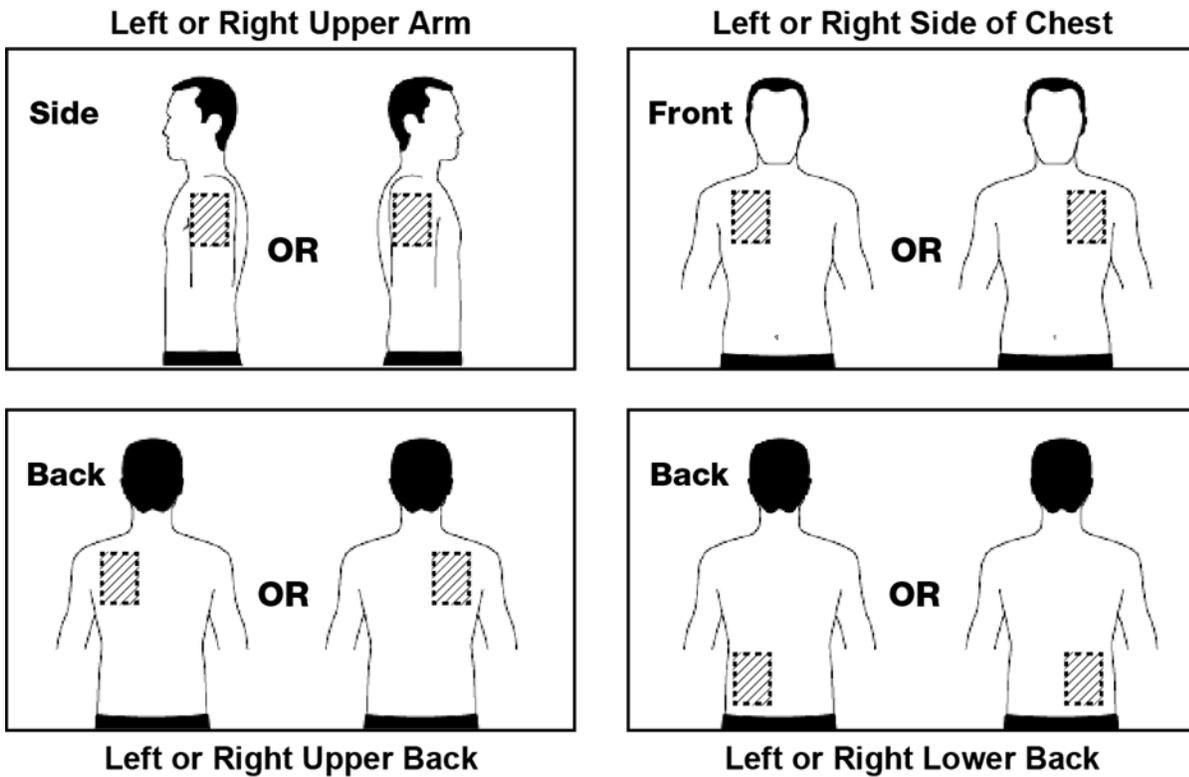
- EXELON PATCH is a thin, beige, plastic patch that sticks to the skin. Each EXELON PATCH is sealed in a pouch that protects it until you are ready to put it on (See Figure A).
- **Only 1 EXELON PATCH should be worn at a time. Do not apply more than 1 EXELON PATCH at a time to the body.**
- Do not open the pouch or remove the EXELON PATCH until you are ready to apply it.

Using EXELON PATCH:

Step 1. Choose an area to apply the EXELON PATCH (See Figure B).

- **Instructions for Caregivers:** Apply EXELON PATCH to the upper **or** lower back if it is likely that the patient will remove it. If this is not a concern, the EXELON PATCH can be applied **instead** to the upper arm **or** chest. Do not apply the EXELON PATCH to areas where it can be rubbed off by tight clothing or belts.
- Only apply the EXELON PATCH to healthy skin that is clean, dry, hairless, and free of redness, irritation, burns or cuts.

Figure B

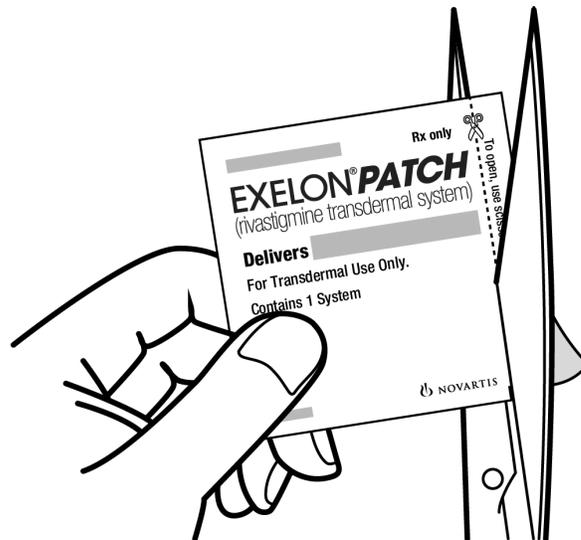


The diagram represents areas on the body where EXELON PATCH may be applied. Only 1 patch should be worn at a time. Do not apply multiple patches to the body.

Step 2. Remove the EXELON PATCH from the pouch (See Figure C).

Carefully cut the pouch along the dotted line to open and remove the EXELON PATCH. Save the pouch for later use.

Figure C

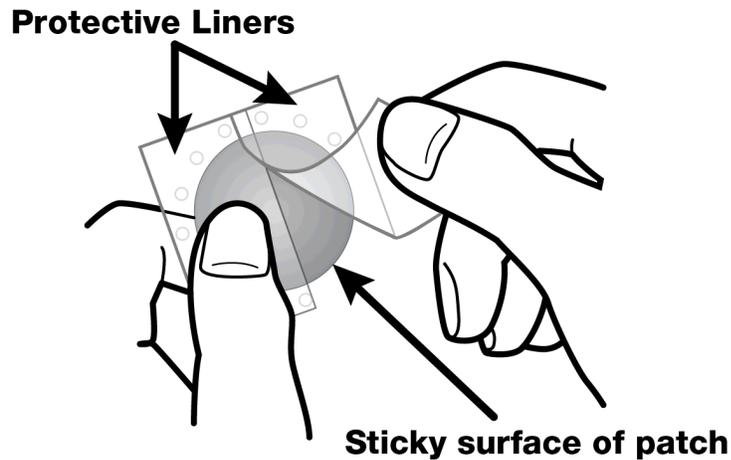


- Do not cut or fold the EXELON PATCH itself.

Step 3. Remove 1 side of the adhesive liner (See Figure D).

- A protective liner covers the sticky (adhesive) side of the EXELON PATCH. Peel off 1 side of the protective cover. Do not touch the sticky part of the EXELON PATCH with your fingers.

Figure D



Step 4. Apply the EXELON PATCH to your skin (See Figure E).

- Apply the sticky (adhesive) side of the EXELON PATCH to your chosen area of skin **and** then peel off the other side of the protective cover.

Figure E



- **Press down on the EXELON PATCH firmly for 30 seconds to make sure that the edges stick to your skin (See Figure F).**

Figure F



Step 5: Wash your hands with soap and water right away.

Note:

- If your EXELON PATCH falls off, select a new area, and repeat Steps 2 to 5 to apply a new EXELON PATCH.
- Be sure to replace the new EXELON PATCH the next day at the same time as usual.

Removing your EXELON PATCH:

Step 6. Remove the EXELON PATCH from the skin (See Figure G).

- Gently pull on 1 edge of the EXELON PATCH to remove it from your skin.

Figure G



Throwing away the used EXELON PATCH:

Step 7. Throw away the used EXELON PATCH (See Figure H).

- Fold the used EXELON PATCH in half (with the sticky sides together) and put it back into the pouch that you saved.

Figure H



- Throw away the used EXELON PATCH safely and out of the reach of children and pets.
- Some medicine stays in the patch for 24 hours after you use it and should be folded together (sticky side together) and safely thrown away. **Do not try to re-use EXELON PATCHes.**

Step 8: Wash your hands with soap and water right away.

- After you remove the EXELON PATCH, if any adhesive remains on your skin, you can use soap and water or an oil-based substance (such as baby oil) to remove the adhesive. Alcohol or other dissolving liquids (such as nail polish remover) should not be used.

This Instructions for Use have been approved by the U.S. Food and Drug Administration.

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