

Patient Information
Rivastigmine (RIV-a-STIG-meen)
Transdermal System

What is the most important information I should know about Rivastigmine Transdermal System?
Rivastigmine Transdermal System is for skin use only.

What is Rivastigmine Transdermal System?

Rivastigmine Transdermal System 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, Rivastigmine Transdermal System was shown to help with cognition which includes (memory, understanding communication and reasoning) and with doing daily tasks. Rivastigmine Transdermal System does not work the same in all people. Some people treated with Rivastigmine Transdermal System 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 Rivastigmine Transdermal System. Rivastigmine Transdermal System does not cure Alzheimer's disease. All patients with Alzheimer's disease get worse over time.

Rivastigmine Transdermal System comes as a transdermal system that delivers rivastigmine (the medicine in Rivastigmine Transdermal System) through the skin.

It is not known if Rivastigmine Transdermal System is safe or effective in children under 18 years of age.

Who should not use Rivastigmine Transdermal System?

Do not use Rivastigmine Transdermal System if you:

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

Ask your healthcare provider if you are not sure if you should use Rivastigmine Transdermal System.

What should I tell my healthcare provider before using Rivastigmine Transdermal System?

Before you use Rivastigmine Transdermal System, 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 Rivastigmine Transdermal System) in the past.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if the medicine in Rivastigmine Transdermal System 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 Rivastigmine Transdermal System passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take Rivastigmine Transdermal System.

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 Rivastigmine Transdermal System, inform your doctor because Rivastigmine Transdermal System may exaggerate the effects of anesthesia, or the effects of a betablocker, 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 Rivastigmine Transdermal System?

- Use Rivastigmine Transdermal System exactly as your healthcare provider tells you to use it.
- Rivastigmine Transdermal Systems come in 3 different dosage strengths.
- Your healthcare provider may change your dose as needed
- Wear only 1 Rivastigmine Transdermal System at a time.
- Rivastigmine Transdermal System is for skin use only.
- Only apply Rivastigmine Transdermal System to healthy skin that is clean, dry, hairless, and free of redness, irritation, burns or cuts.
- Avoid applying Rivastigmine Transdermal System to areas on your body that will be rubbed against tight clothing.
- Do not apply Rivastigmine Transdermal System to skin that has cream, lotion, or powder on it.
- Change your Rivastigmine Transdermal System every 24 hours at the same time of day. You may write the date and time you put on the Rivastigmine Transdermal System 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 Rivastigmine Transdermal System has become loose when you are bathing, swimming, or showering.

- Rivastigmine Transdermal System is designed to deliver medication during the time it is worn. If your Rivastigmine Transdermal System falls off before its usual replacement time, put on a new rivastigmine transdermal system 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 Rivastigmine Transdermal System that has become loose or try to reapply an Rivastigmine Transdermal System that has fallen off.
- If you miss a dose or forget to change your Rivastigmine Transdermal System apply your next Rivastigmine Transdermal System as soon as you remember. Do not apply 2 rivastigmine transdermal systems to make up for the missed dose.
- If you miss more than 3 doses of applying Rivastigmine Transdermal System, call your healthcare provider before putting on a new Rivastigmine Transdermal System. You may need to restart Rivastigmine Transdermal System at a lower dose.
- Always remove the old Rivastigmine Transdermal System from the previous day before you apply a new one.
- **Having more than 1 Rivastigmine Transdermal System on your body at the same time can cause you to get too much medicine.** If you accidentally use more than 1 Rivastigmine Transdermal System 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 Rivastigmine Transdermal System?

- Do not touch your eyes after you touch the Rivastigmine Transdermal System. 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.
- Rivastigmine Transdermal System can cause drowsiness, dizziness, weakness, or fainting. Do not drive, operate heavy machinery, or do other dangerous activities until you know how Rivastigmine Transdermal System 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 Rivastigmine Transdermal System?

Rivastigmine Transdermal System 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 Rivastigmine Transdermal System be removed before you apply a new one. Do not wear more than 1 Rivastigmine Transdermal System 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 Rivastigmine Transdermal System. Stop using Rivastigmine Transdermal System 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 Rivastigmine Transdermal System 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 Rivastigmine Transdermal System. 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 Rivastigmine Transdermal System?

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

Keep Rivastigmine Transdermal System and all medicines out of the reach of children.

General information about the safe and effective use of Rivastigmine Transdermal System.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use Rivastigmine Transdermal System for a condition for which it was not prescribed. Do not give Rivastigmine Transdermal System 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 Rivastigmine Transdermal System. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Rivastigmine Transdermal System that is written for health professionals.

For more information, go to www.bpirx.com or call 1-800-367-3395.

What are the ingredients of Rivastigmine Transdermal System?

Active ingredient: rivastigmine

Excipients include: acrylic adhesive (applied to a flexible polymer backing film), acrylates copolymer, silicone adhesive.

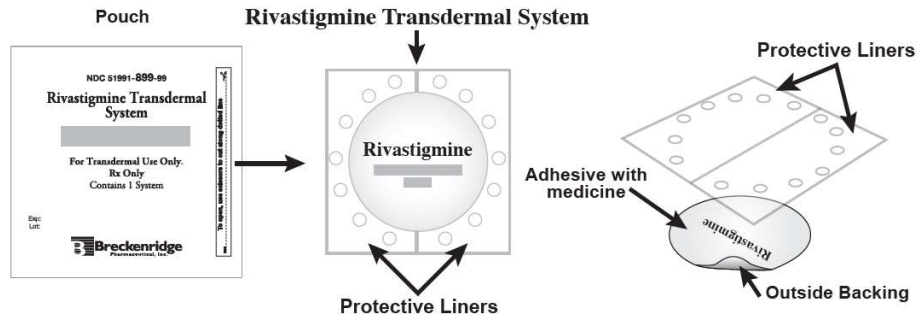
-----Revised: 12/2023

Instructions for Use Rivastigmine (RIV-a-STIG-meen) Transdermal System

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

Rivastigmine Transdermal System is supplied in cartons containing 30 patches (See Figure A)

Figure A



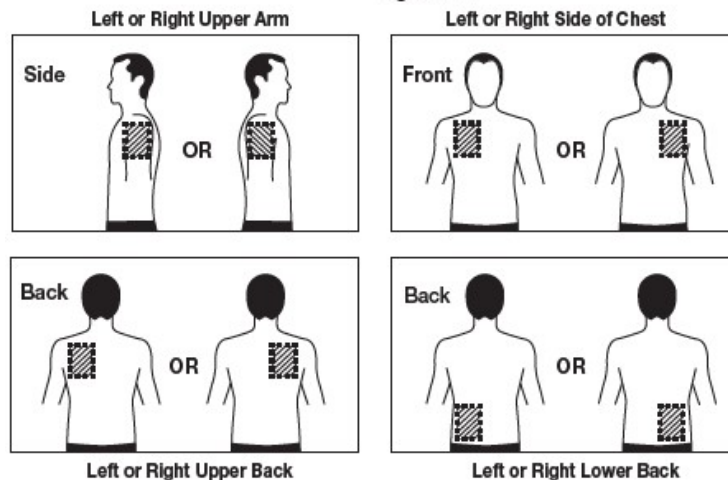
- Rivastigmine Transdermal System is a thin, transparent, plastic patch that sticks to the skin. Each Rivastigmine Transdermal System is sealed in a pouch that protects it until you are ready to put it on (See Figure A).
- **Only 1 Rivastigmine Transdermal System should be worn at a time. Do not apply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

Using Rivastigmine Transdermal System:

Step 1. Choose an area to apply the Rivastigmine Transdermal System (See Figure B).

- **Instructions for Caregivers:** Apply Rivastigmine Transdermal System to the upper **or** lower back if it is likely that the patient will remove it. If this is not a concern, the Rivastigmine Transdermal System can be applied **instead** to the upper arm **or** chest. Do not apply the Rivastigmine Transdermal System to areas where it can be rubbed off by tight clothing or belts.
- Only apply the Rivastigmine Transdermal System 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 Rivastigmine Transdermal System may be applied. Only 1 patch should be worn at a time. Do not apply multiple patches to the body.

Step 2. Remove the Rivastigmine Transdermal System from the pouch (See Figure C).

Carefully cut the pouch along the dotted line to open and remove the Rivastigmine Transdermal System. Save the pouch for later use.

Figure C

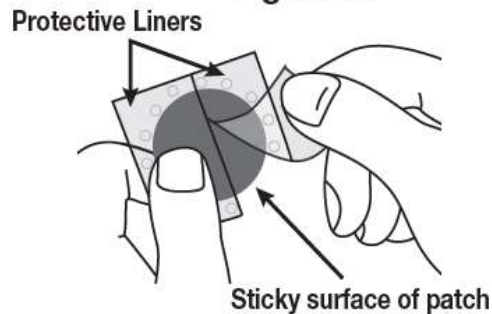


- Do not cut or fold the Rivastigmine Transdermal System itself.

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

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

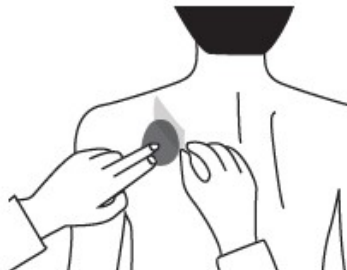
Figure D



Step 4. Apply the Rivastigmine Transdermal System to your skin (See Figure E).

- Apply the sticky (adhesive) side of the Rivastigmine Transdermal System to your chosen area of skin and then peel off the other side of the protective cover.

Figure E



- Press down on the Rivastigmine Transdermal System firmly for 30 seconds to make sure that the edges stick to your skin (See Figure F).

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

Note:

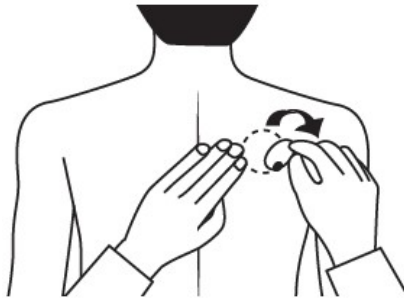
- If your Rivastigmine Transdermal System falls off, select a new area, and repeat Steps 2 to 5 to apply a new Rivastigmine Transdermal System.
- Be sure to replace the new Rivastigmine Transdermal System the next day at the same time as usual.

Removing your Rivastigmine Transdermal System:

Step 6. Remove the Rivastigmine Transdermal System from the skin (See Figure G).

- Gently pull on 1 edge of the Rivastigmine Transdermal System to remove it from your skin.

Figure G



Throwing away the used Rivastigmine Transdermal System:

Step 7. Throw away the used Rivastigmine Transdermal System (See Figure H).

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

Figure H



- Throw away the used Rivastigmine Transdermal System 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 Rivastigmine Transdermal Systems.**

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

- After you remove the Rivastigmine Transdermal System, 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 Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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