

INDICATIONS

RIVAXEL[®] *PATCH* (rivastigmine transdermal system) is a prescription medicine used to treat mild, moderate, and severe memory problems (dementia) associated with Alzheimer's disease.

IMPORTANT SAFETY INFORMATION

- RIVAXEL *PATCH* should not be used if the patient is allergic to any component in RIVAXEL *PATCH*, including the active ingredient rivastigmine. RIVAXEL *PATCH* should also not be used if the patient has had a skin reaction that spread beyond the patch size, had blisters, increased skin redness, or swelling, or did not get better within 48 hours after removal of the RIVAXEL *PATCH*.
- Mistakes in using RIVAXEL[®] *PATCH* (rivastigmine transdermal system) have resulted in serious side effects; some cases have required hospitalization, and rarely, have led to death. Most mistakes have involved not removing the old patch when putting on a new one and the use of multiple patches at one time. Only one RIVAXEL *PATCH* should be worn at a time. If you accidentally apply more than one RIVAXEL *PATCH*, remove all of them and inform the doctor immediately.
- RIVAXEL *PATCH* can also cause serious stomach side effects, including nausea, vomiting, diarrhea, dehydration, decreased appetite, weight loss, and bleeding in your stomach (ulcers).
- Dehydration may result from prolonged vomiting or diarrhea and can be associated with serious outcomes. The incidence and severity of these reactions are dose related. For this reason, treatment should be initiated with RIVAXEL *PATCH* at a dose of 4.6 mg/24 hours and titrated to a dose of 9.5 mg/24 hours, and then 13.3 mg/24 hours, if appropriate. If you have not taken RIVAXEL *PATCH* for more than 3 days, do not start taking it again until you have talked with a doctor.
- Some people have had a skin reaction called allergic contact dermatitis (ACD) when using RIVAXEL *PATCH*. Stop using RIVAXEL *PATCH* and call your health care 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, or peeling or blistering of the skin, which may ooze, drain, or crust over.
- The most common side effects of RIVAXEL *PATCH* include depression, headache, anxiety, dizziness, stomach pain, urinary tract infections, muscle weakness, tiredness, and trouble sleeping.
- Weight should be checked while the person is using RIVAXEL *PATCH*. Weight loss/loss of appetite may occur. People below 50 kg (110 lbs) may experience more side effects and may have to stop using RIVAXEL *PATCH* due to these side effects.
- People at risk for stomach ulcers or who take certain medicines should tell their doctor before starting RIVAXEL *PATCH*, because serious stomach problems, such as bleeding, may occur.
- RIVAXEL *PATCH* may cause fainting or slow heart rate; people with certain heart conditions should tell their doctor before starting therapy. People with serious lung conditions and difficulty breathing, bladder problems, or seizures should consult their doctor before using RIVAXEL *PATCH*. Extrapyrimalidal symptoms (e.g., uncontrollable facial or body movements, including tremor and restlessness) could occur or get worse. Parkinsonian symptoms, particularly tremor, have worsened in Parkinson's disease dementia patients treated with (rivastigmine tartrate) capsules.
- Before using RIVAXEL *PATCH*, people should also tell their doctor about any medical conditions they have, including if they have had a loss of appetite or are losing weight, or if they have had a skin reaction to rivastigmine (the medicine in RIVAXEL *PATCH*) in the past.

- People on RIVAXEL *PATCH* who feel dizzy or drowsy should not drive or use machines.
- Tell the doctor about all other prescription or nonprescription medicines the patient is taking.
- RIVAXEL *PATCH* should not be taken at the same time as metoclopramide (used to treat heartburn, nausea, and vomiting) and with medicines that have a similar effect on the body and the brain (cholinomimetic agents) or with anticholinergic medicines. RIVAXEL *PATCH* should not be taken at the same times as medicines that reduce your blood pressure (beta-blockers). Inform the doctor if the patient needs surgery requiring anesthesia while using RIVAXEL *PATCH*.
- *Please see the patient Information leaflet accompanied with this guide.*

♥ **We are in Jazeera Pharmaceutical Industries pleased to receive an inquiries or any other assistance related to this medicinal product by contacting us via:**

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And; to report any side effects for medicinal products we encourage you to contact the National Pharmacovigilance and drug safety Center (NPC) via:

⇒ **Saudi Arabia**

Fax: +966-11-205-7662

Toll free: 800-249-0000

Unified Number: 19999

Email: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc

⇒ **Other GCC States:**

Please contact the relevant competent authority