

RIVAMENSA Patch 5

RIVAMENSA Patch 10

Rivastigmine (9mg, 18mg)

What is in this leaflet

1. What *RIVAMENSA Patch* is used for
2. How *RIVAMENSA Patch* works
3. Before you use *RIVAMENSA Patch*
4. How to use *RIVAMENSA Patch*
5. While you are using it
6. Side effects
7. Storage and Disposal of *RIVAMENSA Patch*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *RIVAMENSA Patch* is used for

Treatment of patients with mild to moderately severe dementia of the Alzheimer type and severe dementia of the Alzheimer's type.

Treatment of patients with mild to moderately severe dementia associated with Parkinson's disease.

How *RIVAMENSA Patch* works

Rivastigmine improves the function of nerve cells in the brain. It works by preventing the breakdown of a chemical called acetylcholine. People with dementia usually have lower levels of this chemical, which is important for the processes of memory, thinking, and reasoning.

Before you use *RIVAMENSA Patch*

- When you must not use it
 - if you are allergic to rivastigmine or any of the other ingredients of this medicine.
 - if you have ever had an allergic reaction to a similar type of medicine (carbamate derivatives).
 - if you have a skin reaction spreading beyond the patch size, if there is a more intense local reaction (such as blisters, increasing skin inflammation, swelling) and if it does not improve within 48 hours after removal of the transdermal patch.
- If this applies to you, tell your doctor and do not apply *RIVAMENSA Patch*.

- Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor

or pharmacist for advice before taking this medicine.

RIVAMENSA should not be used during pregnancy unless clearly necessary.

You should not breast-feed during treatment with *RIVAMENSA Patch*.

- Before you start to use it

Tell the doctor if you have, or have ever had heart conditions such as irregular or slow heartbeat, OTc prolongation, a family history of OTc prolongation, torsade de pointes, or have low potassium or magnesium. Your doctor may need to monitor you more closely while you are on this medicine.

Talk to your doctor before using *RIVAMENSA*:

- if you have, or have ever had, an active 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 gastrointestinal reactions such as feeling sick (nausea), being sick (vomiting) and diarrhoea. You may become dehydrated (losing too much fluid) if vomiting or diarrhoea are prolonged.
 - 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 more than three days, do not apply the next one before you have talked to your doctor.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

RIVAMENSA might interfere with anticholinergic medicines.

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

Caution when *Rivamensa Patch* is taken together with medicinal product know to prolong the heart's electrical system (OT interval) [including but not limited to quinidine (medicine used to treat irregular heartbeat), amiodarone (medicine used to treat serious/fatal irregular heartbeat), pimozone (medicine works on central nervous system), halofantrine (antimalaria medicine), cisapride (medicine used to treat symptoms of night-time heartburn), citalopram (medicine used to treat depression), mizolastin (antihistamine medicine), medicine used to treat bacterial infection such as moxifloxacin, erythromycin]. Your doctor may also monitor your clinical condition as needed.

How to use *RIVAMENSA Patch*

Always use *RIVAMENSA* patches exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

IMPORTANT:

- Take off the previous patch before putting ONE new patch on.
- Only one patch per day.
- Do not cut the patch into pieces.
- Press the patch firmly in place for at least 30 seconds using the palm of the hand.

- How much to use

Size (cm ²)	API amount	Rivastigmine in vivo release rates per 24 h
5	9 mg	4.6 mg
10	18 mg	9.5 mg

Your doctor will tell you which *RIVAMENSA* is most suitable for you.

- Treatment usually starts with Rivastigmine patch 5 daily
- The recommended usual daily dose is rivastigmine patch 10.
- Only wear one *RIVAMENSA* at a time and replace the patch with a new one after 24 hours.

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

- Where to use it

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 ONE patch per day to ONLY ONE of the possible locations in the following area:

- left upper arm or right upper arm
- left upper chest or right upper chest (avoid breast)
- left upper back or right upper back
- left lower back or right lower back

- How long to use it

To benefit from treatment, you must apply a new patch every day, preferably at the same time of day. Only wear one RIVAMENSA at a time and replace the patch with a new one after 24 hours.

- If you forget to use it

If you forget to change the skin patch, remove it and apply a new one as soon as you remember. **Do not** wear extra patches to make up a missed dose.

Call your doctor for instructions if you miss more than 3 doses of rivastigmine.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital.

Overdose symptoms may include severe forms of some of the side effects listed in this medication guide, examples nausea, vomiting, diarrhea, hypertension and hallucinations.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking RIVAMENSA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

This medication may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

Do not use any cream, lotion, ointment, oil, or powder on the skin where you plan to apply a skin patch. The patch may not stick well to the skin.

Avoid applying heat to the skin where the patch is worn, because it may increase the amount of medicine your body absorbs. Heat sources include hot tubs, heating pads, heat lamps, saunas, heated water beds, and direct sunlight. Avoid touching your eyes after handling a skin patch.

- Things to be careful of

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely.

RIVAMENSA 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.

Side effects

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have a serious side effect such as:

- feeling like you might pass out;
- severe or ongoing vomiting or diarrhea, loss of appetite, weight loss;
- feeling very thirsty or hot, being unable to urinate, heavy sweating, or hot and dry skin;
- black or bloody stools, coughing up blood or vomit that looks like blood or coffee grounds;
- restless muscle movements in your eyes, tongue, jaw, or neck;
- tremors (uncontrolled shaking);
- seizure (convulsions); or

- pain or burning when you urinate.

Less serious side effects may include:

- headache, tired feeling;
- dizziness, spinning feeling;
- anxiety, depressed mood;
- mild nausea or stomach pain;
- muscle weakness;
- sleep problems (insomnia); or
- redness or irritation where the skin patch is worn.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of RIVAMENSA Patch

- Storage

Keep out of the reach and sight of children.

Store in tight container, below 30°C.

- Disposal

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.

Product Description

- What it looks like

Rivamensa patch 5 (9mg as rivastigmine) : Transdermal patch of semi-transparent square shape with rounded corners in patch size of 5cm², with an adhesive film on one side.

Rivamensa patch 10 (18mg as rivastigmine) : Transdermal patch of semi-transparent square shape with rounded corners in patch size of 10cm², with an adhesive film on one side.

- Ingredients

- Active ingredient(s)

Rivastigmine

- Inactive ingredients

Acrylate copolymer adhesive solution

Glacial acetic acid

Allantoin

Ethyl acetate

Polyester/ethylenevinylacetate

lamine film

Polyethylene terephthalate separator

- MAL number::

Rivamensa Patch 5: MAL17107030AZ

Rivamensa Patch 10: MAL17107029AZ

Manufacturer

DAE HWA PHARMACEUTICAL CO.,
LTD.

495, Hanu-ro, Hoengseong-eup,
Hoengseong-gun, Gangwon-do,
Republic of Korea.

Product Registration Holder

MEDISPEC (M) SDN BHD
55 & 57, Lorong Sempadan 2,
11400 Ayer Itam, Penang,
Malaysia

Date of revision

15/07/2025

Serial Number

NPRA(R2/1)220309/846