

Rivacure Patch

Consumer Medication Information Leaflet (RiMUP)

Rivastigmine

4.6 mg/24 h transdermal patch (Rivacure Patch 5)

9.5 mg/24 h transdermal patch (Rivacure Patch 10)

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What Rivacure Patch is use for

Rivacure is used for:

- 1) Mild to moderately severe dementia of the Alzheimer's type
- 2) Severe dementia of Alzheimer's type
- 3) Mild to moderate severe dementia associated with Parkinson's disease.

How Rivacure Patch works

Rivacure belongs to a class of substances called cholinesterase inhibitors. The active substance of Rivacure is rivastigmine. In patients with Alzheimer's dementia, certain nerve cells die in the brain, resulting in low levels of the neurotransmitter acetylcholine (a substance that allows nerve cells to communicate with each other). Rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, Rivacure allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's disease.

Before you use Rivacure Patch

When you must not use it

Do not apply Rivacure Patch

- if you are allergic to rivastigmine (the active substance in Rivacure) 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 Rivacure Patch.

Before you start to use it

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet. Read the following information before you apply Rivacure Patch.

Taking other medicines

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

Rivacure Patch should not be given together with other medicines with similar effects (cholinomimetic agents) or with anticholinergic medicines (such as medicines used to relieve stomach cramps or spasms or to prevent travel sickness).

Rivacure Patch should not be given together with metoclopramide (a medicine used to alleviate or prevent nausea and vomiting). There may be additive effects such as stiff limbs and trembling hands.

If you have to undergo surgery whilst using Rivacure Patch, you should inform your doctor because Rivacure Patch may exaggerate the effects of some muscle relaxants during anaesthesia. Caution when Rivacure Patch is given together with beta-blockers (medicines such as atenolol used to treat hypertension, angina, and

other heart conditions). There may be additive effects such as bradycardia (slow heartbeat) that may result in syncope (fainting, loss of consciousness).

Older people

Age had no impact on the exposure to rivastigmine in Alzheimer's disease patients treated with rivastigmine transdermal patches.

Children and adolescents

Children and adolescents (age below 18 years): Rivastigmine is not recommended for use in children

Pregnancy and Lactation:

Pregnancy

In pregnant animals, rivastigmine and/or metabolites crossed the placenta. It is not known if this occurs in humans. No clinical data on exposed pregnancies are available. In peri/postnatal studies in rats, an increased gestation time was observed. Rivastigmine should not be used during pregnancy unless clearly necessary.

Breast-feeding

In animals, rivastigmine is excreted in milk. It is not known if rivastigmine is excreted into human milk. Therefore, women on rivastigmine should not breast-feed.

How to use Rivacure 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.

How many Rivacure Patches to apply

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 to start treatment

Your doctor will tell you which Rivacure Patch is most suitable for

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you. Treatment usually starts with Rivacure 4.6 mg/24 h.

The recommended usual daily dose is Rivacure 9.5 mg/24 h.

-Only wear one Rivacure patch 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.

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.

Transdermal patch treatment can be resumed at the same dose if treatment is not interrupted for more than three days. Otherwise, your doctor will restart your treatment on Rivacure 4.6 mg/24 h.

Where to apply your Rivacure Patch

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 as following: -

- 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

Every 24 hours take off the previous patch before putting ONE new patch on to ONLY ONE of the possible locations.

When changing the patch, you must remove the previous day's patch before you apply the new one to a different location of skin each time (for example on the right side of your body one day, then on the left side the next day, and on your upper body one day, then on your lower body the next day). Do not apply a new patch

to the same skin area twice within 14 days.

How to apply your Rivacure Patch

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

Carefully remove the existing patch before putting on a new one.

- Each patch is sealed in its own protective sachet. You should only open the sachet when you are ready to apply the patch.

Cut the sachet along the dotted line with scissors and remove the patch from the sachet.

- A protective liner covers the sticky 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.

- Then press the patch firmly in place for at least 30 seconds using the palm of the hand to make sure that the edges stick well.

If it helps you, you may write, for example, the day of the week, on the patch with a thin ball point pen.

Rivacure patch should be worn continuously until it is time to replace it with a new one. You may wish to experiment with different locations when applying a new patch, to find ones that are most comfortable for you and where clothing will not rub on the patch.

How to remove your Rivacure Patch

Gently pull at one edge of the patch to remove it slowly from the skin. In case the adhesive residue is left over on your skin, gently soak the area with warm water and mild soap or use baby oil to remove it. Alcohol or other dissolving liquids (nail polish remover or other solvents) should not be used. You should wash your hands with soap and water after

removing the patch. In case of contact with eyes or if the eyes become red after handling the patch, rinse immediately with plenty of water and seek medical advice if symptoms do not resolve.

What to do if a patch falls off

If a patch falls off, apply a new one for the rest of the day, then replace it at the same time as usual the next day.

When and for how long to apply your Rivacure Patch

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

If you forget to use Rivacure Patch

If you find you have forgotten to apply Rivacure Patch, apply a new patch immediately. You may apply the next patch at the usual time the next day. Do not apply two Rivacure patches to make up for the one that you missed.

If you use more Rivacure Patch than you should (overdose)

If you accidentally apply more than one patch, remove all the patches from your skin, then inform your doctor that you have accidentally applied more than one patch. You may require medical attention. Some people who have accidentally taken too much Rivacure Patch have experienced feeling sick (nausea), being sick (vomiting), diarrhoea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur.

While you are using Rivacure Patch

Things you must do

Take special care with Rivacure Patch

- If you experience gastro-intestinal reactions such as nausea (feeling sick), vomiting (being sick) and diarrhoea. You may become dehydrated (losing too much fluid) if vomiting or diarrhoea are prolonged,

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- If you have, or have ever had an irregular heartbeat,
- 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 (less than 50 kg),
- 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.

Talk to your doctor right away if you have skin inflammation, blisters or swelling of the skin that are increasing and spreading.

If you have not applied Rivacure Patch for several days do not apply the next patch until you have talked to your doctor.

Things you must not do

Do not stop taking Rivacure Patch or change your dose without talking with your doctor. If you have not applied Rivacure Patch for several days do not apply the next patch until you have talked to your doctor.

Things to be careful of

- Bathing, swimming, or showering should not affect the patch. When swimming, you can wear the patch under your swimming costume. Make sure the patch does not loosen during these activities.
- The patch should not be exposed to any external heat sources (excessive sunlight, saunas, solarium) for long periods of time.

Driving and using machines

Alzheimer's disease may cause gradual impairment of driving performance or compromise the ability to use machines. Furthermore, rivastigmine may induce syncope or delirium. As a consequence, rivastigmine has minor or moderate

influence on the ability to drive and use machines. Therefore, in patients with dementia treated with rivastigmine, the ability to continue driving or operating complex machines should be routinely evaluated by the treating physician.

Side Effects

Like all medicines, Rivacure Patch can cause side effects, although not everybody gets them. You may have side effects more often when you start your medicine or when your dose is increased. Usually, the side effects will slowly go away as your body gets used to the medicine.

Take off your patch and tell your doctor straight away, if you notice any of the following side effects which could become serious.

Infections and infestations

Common	Urinary tract infection
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Metabolism and nutrition disorders

Common	Anorexia, decreased appetite
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Uncommon	Dehydration
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Psychiatric disorders

Common	Anxiety, depression, delirium, agitation
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Uncommon	Aggression
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Not known	Hallucinations, restlessness, nightmares
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Nervous system disorders

Common	Headache, syncope, dizziness
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Uncommon	Psychomotor hyperactivity
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Very rare	Extrapyramidal
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	symptoms
Not known	Worsening of Parkinson's disease, seizure, tremor, somnolence

Cardiac disorders

Uncommon	Bradycardia
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Not known	Atrioventricular block, atrial fibrillation, tachycardia, sick sinus syndrome
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Vascular disorders

Not known	Hypertension
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Gastrointestinal disorders

Common	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain
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Uncommon	Gastric ulcer
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Not known	Pancreatitis
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Hepatobiliary disorders

Not known	Hepatitis, elevated liver function tests
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Skin and subcutaneous tissue disorders

Common	Rash
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Not known	Pruritus, erythema, urticaria, vesicles, allergic dermatitis (disseminated)
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Renal and urinary disorders

Common	Urinary incontinence
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General disorders and administration site conditions

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Common	Application site skin reactions (e.g. application site erythema*, application site pruritus*, application site oedema*, application site dermatitis, application site irritation), asthenic conditions (e.g. fatigue, asthenia), pyrexia, weight decreased
Rare	Fall

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Rivacure Patch

Storing

Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month. Store at below 30 °C. Keep out of reach of children. Do not use any patch that is damaged or shows signs of tampering.

Keep pack in sachet until use.

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.

Product Description

What it looks like

Each patch attached with quadrangle beige color protection film and release paper on adhesive layer and labelled with the following:

- “Rivacure Patch 5”
- “Rivacure Patch 10”

Ingredients:

The active substance of Rivacure Patch is rivastigmine. Rivacure Patch 5: each 5 cm² patch contains 9 mg rivastigmine. The release rate is 4.6 mg/24h. Rivacure Patch 10: each 10 cm² patch contains 18 mg rivastigmine. The release rate is 9.5 mg/24h.

The other ingredients are:

- amino methacrylate copolymer, isopropyl myristate, dichloromethane, acrylic adhesive solution, povidone, and ethanol

Pack size:

1 piece per sachet
30 patches per box

Registration Numbers:

Rivacure Patch 5
MAL XXXXXXXXXXAZ
Rivacure Patch 10
MAL XXXXXXXXXXAZ

Manufacturer

ICURE Pharmaceutical Inc
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Product Registration Holder

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