

Not known (frequency cannot be estimated from the available data)

- The signs of Parkinson's disease get worse – such as tremor, stiffness, feeling sleepy and shuffling
- Allergic skin reactions, such as blisters or inflamed skin, itching hives or redness
- Fast heartbeat
- Seeing or hearing things that are not really there (hallucinations)
- High blood pressure
- Changes in tests which show how well the liver is working
- Feeling restless
- Nightmares
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

Other side effects seen with rivastigmine capsules or oral solution and which may occur with the patch:

Common (may affect up to 1 in 10 people):

- Generally feeling unwell
- Feeling confused
- Increased sweating

Rare (may affect up to 1 in 1,000 people):

- Chest pain - this may be caused by heart spasm
- Ulcer in the intestine

Very rare (may affect up to 1 in 10,000 people):

- Bleeding in the gut – shows as blood in stools or when being sick

Not known (frequency cannot be estimated from the available data):

- Some people who have been violently sick have had tearing of the tube that connects your mouth with your stomach (oesophagus)

Reporting of side effects

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 can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rivastigmine contains

Each transdermal patch releases 4.6mg rivastigmine per 24 hours. Each 4.6cm² transdermal patch contains 6.9mg rivastigmine.

Matrix: poly [(2-ethylhexyl)acrylate, vinylacetate] medium molecular weight polyisobutene, high molecular weight polyisobutene, silica, colloidal anhydrous, paraffin, light liquid.

Backing liner: polyethylene/thermoplastic resin/aluminium coated polyester film.

Release liner: polyester film, fluoropolymer-coated Orange printing ink

What Rivastigmine looks like and contents of the pack

Each transdermal patch is a thin, matrix-type transdermal patch. The outside of the backing layer is tan coloured. Each patch is printed in orange with "RIV-TDS 4.6 mg/24 hr". Each pack contains 30 Transdermal patches

Manufacturer and Licence Holder

Manufactured by Luye Pharma AG, Am Windfeld 27 and 35, Miesbach, Bayern 3714, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/2067 - Rivastigmine 4.6 mg/24 hrs transdermal patches

Leaflet revision date: 05/08/25

Blind or partially sighted? Is this leaflet hard to see or read? Phone Lexon (UK) Limited, Tel: 01527 505414 to obtain the leaflet in a format suitable for you.

5. HOW TO STORE RIVASTIGMINE

- Keep out of the sight and reach of children.**
- This medicine does not require any special storage conditions.
- Keep the transdermal patch in the sachet until use.
- Do not** use any patch that is damaged or shows signs of tampering.
- 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.
- Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.
- If your doctor tells you to stop using this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- If your medicine becomes discoloured or shows any other signs of deterioration, ask your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PATIENT INFORMATION LEAFLET

Rivastigmine 4.6 mg/24 hrs transdermal patches (rivastigmine)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is known as Rivastigmine 4.6 mg/24 hrs transdermal patches but will be referred to Rivastigmine throughout the leaflet. Please note that the leaflet also contains information about other strengths of the medicine, Rivastigmine 9.5 mg/24 h transdermal patch.

What is in this leaflet:

- What Rivastigmine is and what it is used for
- What you need to know before you use Rivastigmine
- How to use Rivastigmine
- Possible side effects
- How to store Rivastigmine
- Contents of the pack and other information

1. WHAT RIVASTIGMINE IS AND WHAT IT IS USED FOR

Rivastigmine belongs to a class of substances called cholinesterase inhibitors. 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, rivastigmine allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's disease.

Rivastigmine is used for the treatment of adult patients with mild to moderately severe Alzheimer's dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behaviour.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RIVASTIGMINE

Do not use Rivastigmine

- if you are allergic to rivastigmine (the active substance in Rivastigmine) or any of the other ingredients of this medicine (listed in section 6).
- 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 was 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 Rivastigmine.

Warnings and precautions

Talk to your doctor or pharmacist before using Rivastigmine

- if you have or have ever had a heart condition such as an irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have a low blood level of potassium or magnesium.

- 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.

Other medicines and Rivastigmine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Rivastigmine may increase the effects of some medicines which lower blood pressure e.g. 'beta-blockers', such as atenolol, 'calcium channel antagonists', e.g. amlodipine, nifedipine, 'antiarrhythmic agents' e.g. sotalol, amiodarone, digitalis and pilocarpin, (used to treat glaucoma). This could make you faint.

Caution when Eluden is taken together with other medicines that can affect your heart rhythm or the electrical system of your heart (QT prolongation).

Your doctor may carry out regular checks on your heart in order to ensure that it is working properly if you are also taking any of the following medicines:

- medicines used to treat mental health problems known as 'antipsychotics' e.g. chlorpromazine, levopromazine, sulpiride, amisulpride, tiapride, veralipride, pimozide, haloperidole, droperidole,
- a medicine known as cisapride (used to treat indigestion),
- citalopram (used to treat depression),
- diphenamil (used to treat peptic ulcer),
- halofantrine (used to treat malaria),
- mizolastin (used to treat allergies),
- methadone (a pain relieving medicine, also used in heroin addiction),
- erythromycin IV, pentamidine, moxifloxacin (antibiotics).

Rivastigmine might interfere with anticholinergic medicines, some of which are medicines used to relieve stomach cramps or spasms (e.g. dicyclomine), to treat Parkinson's disease (e.g. amantadine), to treat an overactive bladder (e.g. oxybutynin, tolterodine) or to prevent motion sickness (e.g. diphenhydramine, scopolamine, or meclizine).

If you have to undergo surgery whilst using Rivastigmine transdermal patches, tell your doctor that you are using them, as you may need to stop them because they may exaggerate the effects of some muscle relaxants during anaesthesia.

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.

If you are pregnant, the benefits of using Rivastigmine must be assessed against the possible effects on your unborn child. Rivastigmine **should not** be used during pregnancy unless clearly necessary.

You **should not** breast-feed during treatment with Rivastigmine

Driving and using machines

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

3. HOW TO USE RIVASTIGMINE

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

IMPORTANT:

- **Take off the previous patch before putting ONE new patch on.**
- **Only wear one Rivastigmine 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.**
- **Avoid touching eyes after handling the patch.**

How to start treatment

Your doctor will tell you which Rivastigmine transdermal patch is most suitable for you.

- Treatment usually starts with one Rivastigmine 4.6 mg/24 h.
- The recommended usual daily dose is one Rivastigmine 9.5 mg/24 h. If your condition does not improve after at least 6 months, your doctor may consider increasing the dose to 13.3 mg/24 h (the 13.3 mg/24 h dose strength cannot be achieved with this product. For conditions where this strength should be used, ask your pharmacist for advice).
- Only wear one Rivastigmine at a time and replace the patch with a new one after 24 hours.

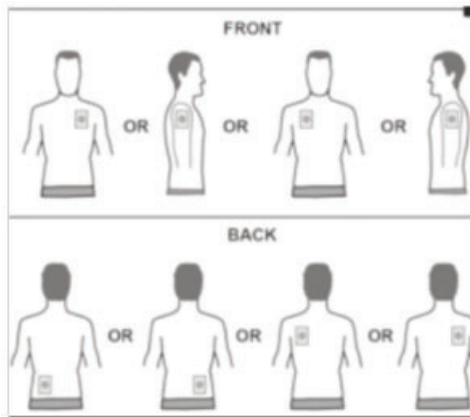
During the course of the treatment your doctor may adjust the dose to suit your individual needs.

If you have not applied a patch for three days or more, do not apply the next one before you have talked to your doctor as you may be more likely to experience side effects. Treatment can be resumed with the same strength patch if you have not applied patches for up to three days. Otherwise your doctor may recommend you continue your treatment with Rivastigmine 4.6 mg/24 h.

Where to apply Rivastigmine

- 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 following locations shown in the following diagram:
 - 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 following 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 chest or upper back one day, then on your lower back the next day). Do not apply a new patch to that same location of skin twice within 14 days.

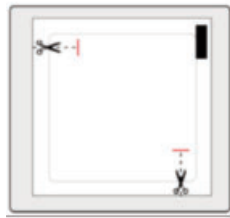
How to apply Rivastigmine

Rivastigmine patches are thin, tan coloured, 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 from the sachet until just before you apply it.



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

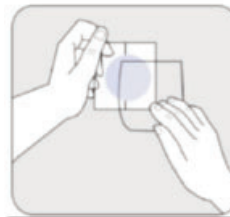
For patients starting treatment for the first time and for patients restarting rivastigmine after treatment interruption, please begin with the second picture.



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 at both scissor marks, but not further than the indicated line. Tear the sachet to open. **Do not** cut the entire length of the sachet in order to avoid damaging of the patch.

Remove the patch from the sachet. Remove the cover sheet from the top, skin-coloured side of the patch and discard it.



A protective liner covers the sticky side of the patch. Peel off one side of the protective liner but 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 or 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.

The patch should be worn continuously until it is time to replace it with a new one. You may wish to experiment with different locations (choosing from those highlighted above) 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 Rivastigmine

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

Washing your hands

You should wash your hands with soap and water after removing or applying a 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.

Can you wear Rivastigmine when you are bathing, swimming, or in the sun?

- Bathing, swimming or showering should not affect the patch. Make sure the patch does not loosen during these activities.
- Do not expose the patch to any external heat sources (e.g. excessive sunlight, saunas, solarium) for long periods of time.

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 Rivastigmine

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

Use in children and adolescents

There is no relevant use of Rivastigmine in the paediatric population in the treatment of Alzheimer's disease.

If you use more Rivastigmine than you should

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 used too much rivastigmine have experienced a decrease in pupil size in the eye (miosis), reddening of the skin and feeling hot (flushing), stomach pain, feeling sick (nausea), being sick (vomiting), diarrhoea, slow heartbeat, sudden difficulty in breathing (bronchospasm), increased phlegm production, increased sweating, incontinence or loss of bowel control, crying, low blood pressure, increase in saliva, dizziness, shaking, headache, feeling sleepy, confusion, high blood pressure, hallucinations and lacking energy (malaise). In severe cases, muscle weakness, muscle twitching, fits and slowed or stopped breathing has been reported.

If you forget to use Rivastigmine

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

If you stop using Rivastigmine

Tell your doctor or pharmacist if you stop using the patch.

If you have not applied a patch for three days or more, do not apply the next one before you have talked to your doctor as you may be more likely to experience side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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:

- Fits (seizures)
- Changes in the rhythm of the heart, which you may notice as a very fast heart rate or a feeling of missing heart beats
- Stomach ulcer (you may have stomach pain and if you are sick it may contain fresh blood, or look like it contains coffee grounds)
- Inflammation of the pancreas – signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- Feeling very confused, which may be associated with seeing, hearing or feeling things that are not there (hallucinations), feeling out of touch with reality (delusion) and increased or decreased activity (delirium)
- Liver disorders (you may notice yellowing of the skin or whites of the eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)

Other possible side effects include:

Common (may affect up to 1 in 10 people):

- Headache
- Lack or loss of appetite, decreased weight
- Feeling anxious, depressed, dizzy
- Fainting
- Feeling sick, being sick, diarrhoea, indigestion/heartburn, stomach ache/pain
- Feeling agitated, tired, generally weak, feverish
- Skin rash and allergic skin reactions where the patch is applied such as eczema like reactions, redness, itching, swelling and irritation
- A urine infection (you may have pain on passing water, or need to go to the loo more often)
- Urinary incontinence (inability to retain adequate urine)

Uncommon (may affect up to 1 in 100 people):

- Problems with your heart such as slow heart-beat
- Dehydration (losing too much fluid)
- Hyperactivity (high level of activity, restlessness)
- Aggression

Rare (may affect up to 1 in 1,000 people):

- Fall

Very rare (may affect up to 1 in 10,000 people):

- Stiff arms or legs, restlessness, muscle spasms, tremor such as trembling hands

Not known (frequency cannot be estimated from the available data)

- The signs of Parkinson's disease get worse – such as tremor, stiffness, feeling sleepy and shuffling
- Allergic skin reactions, such as blisters or inflamed skin, itching hives or redness
- Fast heartbeat
- Seeing or hearing things that are not really there (hallucinations)
- High blood pressure
- Changes in tests which show how well the liver is working
- Feeling restless
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- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

Other side effects seen with rivastigmine capsules or oral solution and which may occur with the patch:

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- Generally feeling unwell
- Feeling confused
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- Chest pain - this may be caused by heart spasm
- Ulcer in the intestine

Very rare (may affect up to 1 in 10,000 people):

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Reporting of side effects

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PATIENT INFORMATION LEAFLET Rivastigmine 4.6 mg/24 hrs transdermal patches (rivastigmine)

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1. WHAT RIVASTIGMINE IS AND WHAT IT IS USED FOR

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Warnings and precautions

Talk to your doctor or pharmacist before using Rivastigmine

- if you have or have ever had a heart condition such as an irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have a low blood level of potassium or magnesium.

- if you have or have ever had an active stomach ulcer.
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- **Press the patch firmly in place for at least 30 seconds using the palm of the hand.**
- **Avoid touching eyes after handling the patch.**

How to start treatment

Your doctor will tell you which Rivastigmine transdermal patch is most suitable for you.

- Treatment usually starts with one Rivastigmine 4.6 mg/24 h.
- The recommended usual daily dose is one Rivastigmine 9.5 mg/24 h. If your condition does not improve after at least 6 months, your doctor may consider increasing the dose to 13.3 mg/24 h (the 13.3 mg/24 h dose strength cannot be achieved with this product. For conditions where this strength should be used, ask your pharmacist for advice).
- Only wear one Rivastigmine at a time and replace the patch with a new one after 24 hours.

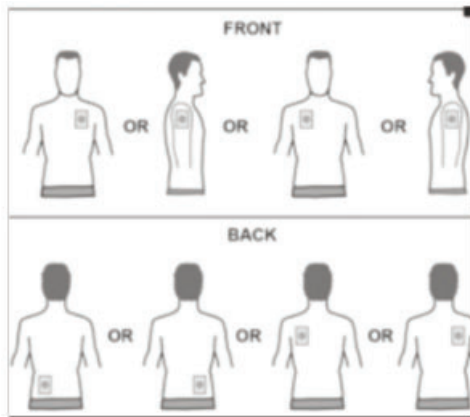
During the course of the treatment your doctor may adjust the dose to suit your individual needs.

If you have not applied a patch for three days or more, do not apply the next one before you have talked to your doctor as you may be more likely to experience side effects. Treatment can be resumed with the same strength patch if you have not applied patches for up to three days. Otherwise your doctor may recommend you continue your treatment with Rivastigmine 4.6 mg/24 h.

Where to apply Rivastigmine

- 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 following locations shown in the following diagram:
 - 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 following 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 chest or upper back one day, then on your lower back the next day). Do not apply a new patch to that same location of skin twice within 14 days.

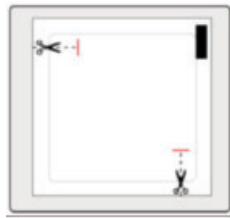
How to apply Rivastigmine

Rivastigmine patches are thin, tan coloured, 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 from the sachet until just before you apply it.



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

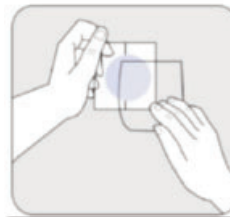
For patients starting treatment for the first time and for patients restarting rivastigmine after treatment interruption, please begin with the second picture.



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 at both scissor marks, but not further than the indicated line. Tear the sachet to open. **Do not** cut the entire length of the sachet in order to avoid damaging of the patch.

Remove the patch from the sachet. Remove the cover sheet from the top, skin-coloured side of the patch and discard it.



A protective liner covers the sticky side of the patch. Peel off one side of the protective liner but 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 or 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.

The patch should be worn continuously until it is time to replace it with a new one. You may wish to experiment with different locations (choosing from those highlighted above) 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 Rivastigmine

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

Washing your hands

You should wash your hands with soap and water after removing or applying a 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.

Can you wear Rivastigmine when you are bathing, swimming, or in the sun?

- Bathing, swimming or showering should not affect the patch. Make sure the patch does not loosen during these activities.
- Do not expose the patch to any external heat sources (e.g. excessive sunlight, saunas, solarium) for long periods of time.

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 Rivastigmine

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

Use in children and adolescents

There is no relevant use of Rivastigmine in the paediatric population in the treatment of Alzheimer's disease.

If you use more Rivastigmine than you should

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 used too much rivastigmine have experienced a decrease in pupil size in the eye (miosis), reddening of the skin and feeling hot (flushing), stomach pain, feeling sick (nausea), being sick (vomiting), diarrhoea, slow heartbeat, sudden difficulty in breathing (bronchospasm), increased phlegm production, increased sweating, incontinence or loss of bowel control, crying, low blood pressure, increase in saliva, dizziness, shaking, headache, feeling sleepy, confusion, high blood pressure, hallucinations and lacking energy (malaise). In severe cases, muscle weakness, muscle twitching, fits and slowed or stopped breathing has been reported.

If you forget to use Rivastigmine

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

If you stop using Rivastigmine

Tell your doctor or pharmacist if you stop using the patch.

If you have not applied a patch for three days or more, do not apply the next one before you have talked to your doctor as you may be more likely to experience side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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:

- Fits (seizures)
- Changes in the rhythm of the heart, which you may notice as a very fast heart rate or a feeling of missing heart beats
- Stomach ulcer (you may have stomach pain and if you are sick it may contain fresh blood, or look like it contains coffee grounds)
- Inflammation of the pancreas – signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- Feeling very confused, which may be associated with seeing, hearing or feeling things that are not there (hallucinations), feeling out of touch with reality (delusion) and increased or decreased activity (delirium)
- Liver disorders (you may notice yellowing of the skin or whites of the eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)

Other possible side effects include:

Common (may affect up to 1 in 10 people):

- Headache
- Lack or loss of appetite, decreased weight
- Feeling anxious, depressed, dizzy
- Fainting
- Feeling sick, being sick, diarrhoea, indigestion/heartburn, stomach ache/pain
- Feeling agitated, tired, generally weak, feverish
- Skin rash and allergic skin reactions where the patch is applied such as eczema like reactions, redness, itching, swelling and irritation
- A urine infection (you may have pain on passing water, or need to go to the loo more often)
- Urinary incontinence (inability to retain adequate urine)

Uncommon (may affect up to 1 in 100 people):

- Problems with your heart such as slow heart-beat
- Dehydration (losing too much fluid)
- Hyperactivity (high level of activity, restlessness)
- Aggression

Rare (may affect up to 1 in 1,000 people):

- Fall

Very rare (may affect up to 1 in 10,000 people):

- Stiff arms or legs, restlessness, muscle spasms, tremor such as trembling hands

Not known (frequency cannot be estimated from the available data)

- The signs of Parkinson's disease get worse – such as tremor, stiffness, feeling sleepy and shuffling
- Allergic skin reactions, such as blisters or inflamed skin, itching hives or redness
- Fast heartbeat
- Seeing or hearing things that are not really there (hallucinations)
- High blood pressure
- Changes in tests which show how well the liver is working
- Feeling restless
- Nightmares
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

Other side effects seen with rivastigmine capsules or oral solution and which may occur with the patch:

Common (may affect up to 1 in 10 people):

- Generally feeling unwell
- Feeling confused
- Increased sweating

Rare (may affect up to 1 in 1,000 people):

- Chest pain - this may be caused by heart spasm
- Ulcer in the intestine

Very rare (may affect up to 1 in 10,000 people):

- Bleeding in the gut – shows as blood in stools or when being sick

Not known (frequency cannot be estimated from the available data):

- Some people who have been violently sick have had tearing of the tube that connects your mouth with your stomach (oesophagus)

Reporting of side effects

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 can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rivastigmine contains

Each transdermal patch releases 4.6mg rivastigmine per 24 hours. Each 4.6cm² transdermal patch contains 6.9mg rivastigmine.

Matrix: poly [(2-ethylhexyl)acrylate, vinylacetate] medium molecular weight polyisobutene, high molecular weight polyisobutene, silica, colloidal anhydrous, paraffin, light liquid.

Backing liner: polyethylene/thermoplastic resin/aluminium coated polyester film.

Release liner: polyester film, fluoropolymer-coated
Orange printing ink

What Rivastigmine looks like and contents of the pack

Each transdermal patch is a thin, matrix-type transdermal patch. The outside of the backing layer is tan coloured. Each patch is printed in orange with "RIV-TDS 4.6 mg/24 hr". Each pack contains 30 Transdermal patches

Manufacturer and Licence Holder

Manufactured by Luye Pharma AG (Bayern – DE), am Windfeld 27 and 35, Miesbach, Bayern, 83714, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/2067 - Rivastigmine 4.6 mg/24 hrs transdermal patches

Leaflet revision date: 05/08/25

**Blind or partially sighted?
Is this leaflet hard to see or read? Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you.**

5. HOW TO STORE RIVASTIGMINE

- **Keep out of the sight and reach of children.**
- This medicine does not require any special storage conditions.
- Keep the transdermal patch in the sachet until use.
- **Do not** use any patch that is damaged or shows signs of tampering.
- 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.
- Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.
- If your doctor tells you to stop using this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- If your medicine becomes discoloured or shows any other signs of deterioration, ask your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PATIENT INFORMATION LEAFLET Rivastigmine 4.6 mg/24 hrs transdermal patches (rivastigmine)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is known as Rivastigmine 4.6 mg/24 hrs transdermal patches but will be referred to Rivastigmine throughout the leaflet. Please note that the leaflet also contains information about other strengths of the medicine, Rivastigmine 9.5 mg/24 h transdermal patch.

What is in this leaflet:

1. What Rivastigmine is and what it is used for
2. What you need to know before you use Rivastigmine
3. How to use Rivastigmine
4. Possible side effects
5. How to store Rivastigmine
6. Contents of the pack and other information

1. WHAT RIVASTIGMINE IS AND WHAT IT IS USED FOR

Rivastigmine belongs to a class of substances called cholinesterase inhibitors. 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, rivastigmine allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's disease.

Rivastigmine is used for the treatment of adult patients with mild to moderately severe Alzheimer's dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behaviour.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RIVASTIGMINE

Do not use Rivastigmine

- if you are allergic to rivastigmine (the active substance in Rivastigmine) or any of the other ingredients of this medicine (listed in section 6).
- 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 was 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 Rivastigmine.

Warnings and precautions

Talk to your doctor or pharmacist before using Rivastigmine

- if you have or have ever had a heart condition such as an irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have a low blood level of potassium or magnesium.

- 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.

Other medicines and Rivastigmine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Rivastigmine may increase the effects of some medicines which lower blood pressure e.g. 'beta-blockers', such as atenolol, 'calcium channel antagonists', e.g. amlodipine, nifedipine, 'antiarrhythmic agents' e.g. sotalol, amiodarone, digitalis and pilocarpin, (used to treat glaucoma). This could make you faint.

Caution when Eluden is taken together with other medicines that can affect your heart rhythm or the electrical system of your heart (QT prolongation).

Your doctor may carry out regular checks on your heart in order to ensure that it is working properly if you are also taking any of the following medicines:

- medicines used to treat mental health problems known as 'antipsychotics' e.g. chlorpromazine, levopromazine, sulpiride, amisulpride, tiapride, veralipride, pimoziide, haloperidole, droperidole,
- a medicine known as cisapride (used to treat indigestion),
- citalopram (used to treat depression),
- diphemanil (used to treat peptic ulcer),
- halofantrine (used to treat malaria),
- mizolastin (used to treat allergies),
- methadone (a pain relieving medicine, also used in heroin addiction),
- erythromycin IV, pentamidine, moxifloxacin (antibiotics).

Rivastigmine might interfere with anticholinergic medicines, some of which are medicines used to relieve stomach cramps or spasms (e.g. dicyclomine), to treat Parkinson's disease (e.g. amantadine), to treat an overactive bladder (e.g. oxybutynin, tolterodine) or to prevent motion sickness (e.g. diphenhydramine, scopolamine, or meclizine).

If you have to undergo surgery whilst using Rivastigmine transdermal patches, tell your doctor that you are using them, as you may need to stop them because they may exaggerate the effects of some muscle relaxants during anaesthesia.

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.

If you are pregnant, the benefits of using Rivastigmine must be assessed against the possible effects on your unborn child. Rivastigmine **should not** be used during pregnancy unless clearly necessary.

You **should not** breast-feed during treatment with Rivastigmine

Driving and using machines

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

3. HOW TO USE RIVASTIGMINE

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

IMPORTANT:

- **Take off the previous patch before putting ONE new patch on.**
- **Only wear one Rivastigmine 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.**
- **Avoid touching eyes after handling the patch.**

How to start treatment

Your doctor will tell you which Rivastigmine transdermal patch is most suitable for you.

- Treatment usually starts with one Rivastigmine 4.6 mg/24 h.
- The recommended usual daily dose is one Rivastigmine 9.5 mg/24 h. If your condition does not improve after at least 6 months, your doctor may consider increasing the dose to 13.3 mg/24 h (the 13.3 mg/24 h dose strength cannot be achieved with this product. For conditions where this strength should be used, ask your pharmacist for advice).
- Only wear one Rivastigmine at a time and replace the patch with a new one after 24 hours.

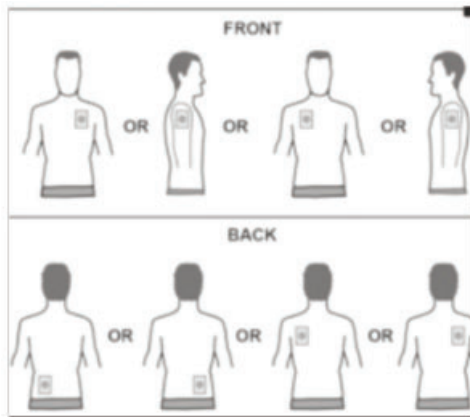
During the course of the treatment your doctor may adjust the dose to suit your individual needs.

If you have not applied a patch for three days or more, do not apply the next one before you have talked to your doctor as you may be more likely to experience side effects. Treatment can be resumed with the same strength patch if you have not applied patches for up to three days. Otherwise your doctor may recommend you continue your treatment with Rivastigmine 4.6 mg/24 h.

Where to apply Rivastigmine

- 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 following locations shown in the following diagram:
 - 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 following 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 chest or upper back one day, then on your lower back the next day). Do not apply a new patch to that same location of skin twice within 14 days.

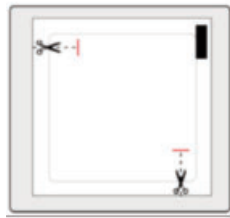
How to apply Rivastigmine

Rivastigmine patches are thin, tan coloured, 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 from the sachet until just before you apply it.



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

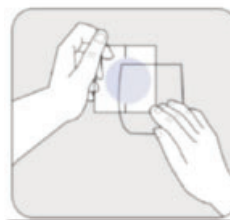
For patients starting treatment for the first time and for patients restarting rivastigmine after treatment interruption, please begin with the second picture.



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 at both scissor marks, but not further than the indicated line. Tear the sachet to open. **Do not** cut the entire length of the sachet in order to avoid damaging of the patch.

Remove the patch from the sachet. Remove the cover sheet from the top, skin-coloured side of the patch and discard it.



A protective liner covers the sticky side of the patch. Peel off one side of the protective liner but 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 or 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.

The patch should be worn continuously until it is time to replace it with a new one. You may wish to experiment with different locations (choosing from those highlighted above) 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 Rivastigmine

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

Washing your hands

You should wash your hands with soap and water after removing or applying a 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.

Can you wear Rivastigmine when you are bathing, swimming, or in the sun?

- Bathing, swimming or showering should not affect the patch. Make sure the patch does not loosen during these activities.
- Do not expose the patch to any external heat sources (e.g. excessive sunlight, saunas, solarium) for long periods of time.

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 Rivastigmine

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

Use in children and adolescents

There is no relevant use of Rivastigmine in the paediatric population in the treatment of Alzheimer's disease.

If you use more Rivastigmine than you should

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 used too much rivastigmine have experienced a decrease in pupil size in the eye (miosis), reddening of the skin and feeling hot (flushing), stomach pain, feeling sick (nausea), being sick (vomiting), diarrhoea, slow heartbeat, sudden difficulty in breathing (bronchospasm), increased phlegm production, increased sweating, incontinence or loss of bowel control, crying, low blood pressure, increase in saliva, dizziness, shaking, headache, feeling sleepy, confusion, high blood pressure, hallucinations and lacking energy (malaise). In severe cases, muscle weakness, muscle twitching, fits and slowed or stopped breathing has been reported.

If you forget to use Rivastigmine

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

If you stop using Rivastigmine

Tell your doctor or pharmacist if you stop using the patch. If you have not applied a patch for three days or more, do not apply the next one before you have talked to your doctor as you may be more likely to experience side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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:

- Fits (seizures)
- Changes in the rhythm of the heart, which you may notice as a very fast heart rate or a feeling of missing heart beats
- Stomach ulcer (you may have stomach pain and if you are sick it may contain fresh blood, or look like it contains coffee grounds)
- Inflammation of the pancreas – signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- Feeling very confused, which may be associated with seeing, hearing or feeling things that are not there (hallucinations), feeling out of touch with reality (delusion) and increased or decreased activity (delirium)
- Liver disorders (you may notice yellowing of the skin or whites of the eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)

Other possible side effects include:

Common (may affect up to 1 in 10 people):

- Headache
- Lack or loss of appetite, decreased weight
- Feeling anxious, depressed, dizzy
- Fainting
- Feeling sick, being sick, diarrhoea, indigestion/heartburn, stomach ache/pain
- Feeling agitated, tired, generally weak, feverish
- Skin rash and allergic skin reactions where the patch is applied such as eczema like reactions, redness, itching, swelling and irritation
- A urine infection (you may have pain on passing water, or need to go to the loo more often)
- Urinary incontinence (inability to retain adequate urine)

Uncommon (may affect up to 1 in 100 people):

- Problems with your heart such as slow heart-beat
- Dehydration (losing too much fluid)
- Hyperactivity (high level of activity, restlessness)
- Aggression

Rare (may affect up to 1 in 1,000 people):

- Fall

Very rare (may affect up to 1 in 10,000 people):

- Stiff arms or legs, restlessness, muscle spasms, tremor such as trembling hands