

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.



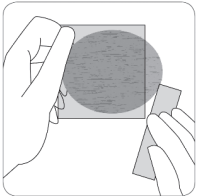
Then press the patch firmly in place for about 15 seconds using the palm of the hand to make sure that the edges stick well.

Continue with the application of the **oval** adhesive cover.

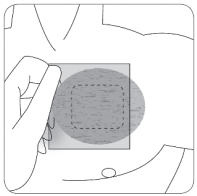


Cut the second, bigger sachet at both scissors marks, but not further than the indicated line. Tear the sachet to open. Do not cut the entire length of the sachet in order to avoid damaging of the drug-free adhesive cover.

Remove the oval, beige adhesive cover from the sachet.



A protective liner covers the sticky side of the patch.
Peel off the smaller side of the protective liner and do not touch the sticky part of the patch with the fingers.



Place the adhesive cover with the sticky side on the already attached transdermal patch so that this is completely covered and peel off the second half of the protective liner.



Then press the patch firmly at least for 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 adhesive cover 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 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 Zeyzelf® Twice weekly transdermal patch

Gently pull at one edge of the adhesive cover to remove it slowly together with the transdermal patch from the skin.

If the transdermal patch remains on the skin, gently pull at one edge until it is completely detached 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 patches. 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 your Zeyzelf® Twice weekly transdermal patch 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, then replace it at the same time as usual.

When and for how long to apply your Zeyzelf® Twice weekly transdermal patch?

- To benefit from treatment, you must apply a new patch Twice weekly, latest after four days, preferably at the same time of day.
- Only wear one rectangular transdermal patch and an oval adhesive cover at a time and replace the patch with a new one Twice weekly on **two fix days**.

If you use more Zeyzelf® Twice weekly than you should

If you accidentally apply more than one **rectangular** transdermal 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 rivastigmine have experienced feeling sick (nausea), being sick (vomiting), diarrhoea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur.

If you forget to use Zeyzelf® Twice weekly

If you find you have forgotten to apply a patch, apply one immediately, if treatment has not been interrupted for more than three days.

Replace then this patch at the usual time the usual day to come back to your dosage scheme.

Do not apply two transdermal patches to make up for the one that you missed. 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.

If you stop using Zeyzelf® Twice weekly

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

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:

Common (may affect up to 1 in 10 people)

- loss of appetite
- feeling dizzy
- feeling agitated or sleepy
- urinary incontinence (inability to retain adequate urine)

Uncommon (may affect up to 1 in 100 people)

- problems with your heartbeat such as slow heartbeat
- seeing things that are not really there (hallucinations)
- stomach ulcer
- dehydration (losing too much fluid)
- hyperactivity (high level of activity, restlessness)
- aggression

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

- falling

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

- stiff arms or legs
- trembling hands

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

- allergic reaction where the patch was used, such as blisters or inflamed skin
- the signs of Parkinson's disease get worse – such as tremor, stiffness and shuffling, Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)
- inflammation of the pancreas – signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- fast or uneven heartbeat
- high blood pressure
- fits (seizures)
- liver disorders (yellow skin, yellowing of the whites of the eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)
- changes in tests which show how well the liver is working
- feeling restless
- nightmares

Take off your patch and tell your doctor straight away, if you notice any of the side effects above.

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)

- too much saliva
- loss of appetite
- feeling restless
- generally feeling unwell
- trembling or feeling confused
- increased sweating

Uncommon (may affect up to 1 in 100 people)

- uneven heart rate (e.g. fast heart rate)
- difficulty sleeping
- accidental falls

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

- fits (seizures)
- ulcer in the intestine
- chest pain this may be caused by heart spasm

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

- high blood pressure
- inflammation of the pancreas – the signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- bleeding in the gut – shows as blood in stools or when being sick
- seeing things that are not there (hallucinations)
- 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 or pharmacist. 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.

5. How to store Zeyzelf® Twice weekly

- Keep this medicine out of the sight and reach of children.
- 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.
- This medicine does not require any special storage conditions.
- 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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zeyzelf® Twice weekly contains

The active substance is rivastigmine.

Zeyzelf® Twice weekly 4.6 mg/24 h transdermal patches:

Each transdermal patch releases 4.6 mg of rivastigmine per 24 hours.
Each transdermal patch of 10.8 cm² contains 25.92 mg of rivastigmine.

Zeyzelf® Twice weekly 9.5 mg/24 h transdermal patches:

Each transdermal patch releases 9.5 mg of rivastigmine per 24 hours.
Each transdermal patch of 21.6 cm² contains 51.84 mg of rivastigmine.

The other ingredients of the transdermal patch are:

Backing film: polyethylene terephthalate film

Active layer: tocopherol, poly[(2-ethylhexyl)acrylate, vinylacetate (1:1)]; copolymer of butyl acrylate and butyl methacrylate

Drug permeable membrane: polyethylene film

Adhesive layer: medium molecular weight polyisobutylene, high molecular weight polyisobutylene, polybutene

Release liner: silicoinised polyester film

Blue printing ink

What Zeyzelf® Twice weekly looks like and contents of the pack

Each transdermal patch is a thin patch of rectangular shape with rounded corners. The patch is translucent and labelled with the following:

- Zeyzelf® Twice weekly 4.6 mg/24 h transdermal patches: *RID-TDS 4.6 mg/24 h*
- Zeyzelf® Twice weekly 9.5 mg/24 h transdermal patches: *RID-TDS 9.5 mg/24 h*

The transdermal patches are sealed separately in sachets. The sachets are labelled with the following:

- Zeyzelf® Twice weekly 4.6 mg/24 h transdermal patches
- Zeyzelf® Twice weekly 9.5 mg/24 h transdermal patches

In addition to each transdermal patch adhesive covers for fixation are in the pack.

Each adhesive cover is a thin, beige patch of oval shape.

The adhesive covers are sealed separately in sachets. The sachets are labelled with the following: Adhesive cover without active ingredient

Zeyzelf® Twice weekly transdermal patches are available in packs containing 2, 8, 16 or 24 transdermal patches and 2, 8, 16 or 24 adhesive covers.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

Luye Pharma Ltd., 40 Occam Road, Guildford, GU2 7YG, UK

Manufacturer

Luye Pharma AG, Am Windfeld 35, 83714 Miesbach, Germany

This leaflet was last revised in: November 2024

You can order a patient diary and patient reminder card to help you use your Rivastigmine Luye transdermal patches free of charge from Luye Pharma Ltd., 40 Occam Road, Guildford, GU2 7YG, UK, at safety@luyepharma.co.uk or via phone: 0203 992 7900.



Pharma