Package leaflet: Information for the patient

Zeyzelf® Twice weekly 4.6 mg/24 h transdermal patch
Zeyzelf® Twice weekly 9.5 mg/24 h transdermal patch

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Zeyzelf® Twice weekly is and what it is used for
2. What you need to know before you use Zeyzelf® Twice weekly
3. How to use Zeyzelf® Twice weekly
4. Possible side effects
5. How to store Zeyzelf® Twice weekly
6. Contents of the pack and other information

1. What Zeyzelf® Twice weekly is and what it is used for

The active substance Zeyzelf® Twice weekly is rivastigmine.

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.

Zeyzelf®Twice weekly 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 Zeyzelf® Twice weekly

Do not use Zeyzelf® Twice weekly
- if you are allergic to rivastigmine (the active substance in Zeyzelf® Twice weekly) 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 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 Zeyzelf® Twice weekly transdermal patches.

Warnings and precautions
Talk to your doctor before using Zeyzelf® Twice weekly
- 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.

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.

Carefully remove any existing patch before putting on a new one. Do not apply more than one patch at the same time. Having multiple (or more than one) transdermal patches on your body could expose you to more amount of this medicine than you should.

Children and adolescents
There is no relevant use of Zeyzelf® Twice weekly in the paediatric population in the treatment of Alzheimer's disease.

Other medicines and Zeyzelf® Twice weekly
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Zeyzelf® Twice weekly 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) or to prevent motion sickness (e.g. diphenhydramine, scopolamine, or meclizine).

Zeyzelf® Twice weekly patch should not be given at the same time as metoclopramide (a medicine used to relieve or prevent nausea and vomiting). Taking the two medicines together could cause problems such as stiff limbs and trembling hands.

If you have to undergo surgery whilst using Zeyzelf® Twice weekly transdermal patches, tell your doctor that you are using them because they may exaggerate the effects of some muscle relaxants during anaesthesia.

Caution when Zeyzelf® Twice weekly patch is given together with beta-blockers (medicines such as atenolol used to treat hypertension, angina, and other heart conditions). Taking the two medicines together could cause problems such as slowing of the heartbeat (bradycardia) leading to fainting or loss of consciousness.

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

Pregnancy, breast-feeding and fertility
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 Zeyzelf® Twice weekly must be assessed against the possible effects on your unborn child. Zeyzelf® Twice weekly should not be used during pregnancy unless clearly necessary.

You should not breast-feed during treatment with Zeyzelf® Twice weekly transdermal patches.

Driving and using machines
Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Zeyzelf® Twice weekly transdermal patches 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 Zeyzelf® Twice weekly

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

How to start treatment
Your doctor will tell you which Zeyzelf® Twice weekly transdermal patch is most suitable for you.

- Treatment usually starts with Zeyzelf® Twice weekly 4.6 mg/24 h.
- The recommended usual daily dose is 9.5 mg/24 h. If well tolerated, the treating physician may consider increasing the dose to 13.3 mg/24 h. The 13.3 mg/24 h dose strength cannot be achieved with Zeyzelf® Twice weekly. For conditions where this strength should be used, other rivastigmine containing transdermal patches of the 13.3 mg/24 h strength are available.
- Only wear one **rectangular** transdermal patch and one oval adhesive cover at a time (as described in detail below) and replace them Twice a week, at the latest after 4 days.

You should change the patches on two fixed days:

Each on
Monday and Friday OR
Tuesday and Saturday OR
Wednesday and Sunday OR
Thursday and Monday OR
Friday and Tuesday OR
Saturday and Wednesday OR
Sunday and Thursday.

Always change the patches at the same time of the day. As a reminder, you should note these days and the time of day.

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

If you have not applied a transdermal 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 Zeyzelf® Twice weekly 4.6 mg/24 h.

Zeyzelf® Twice weekly can be used with food, drink and alcohol.

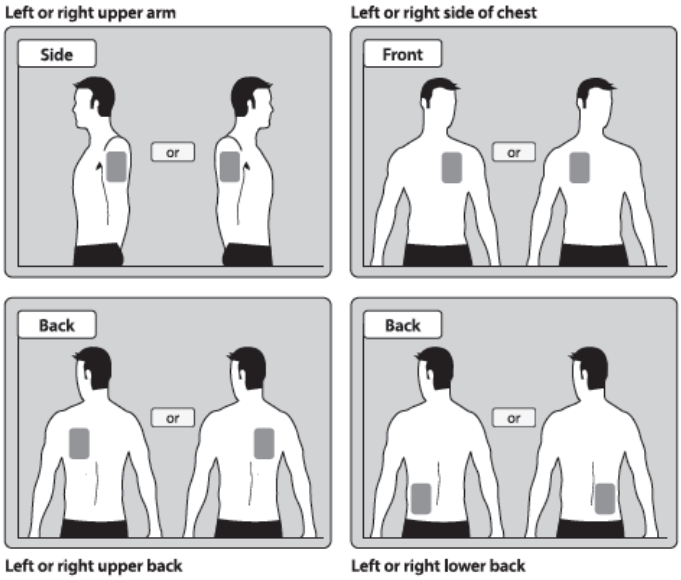
Where to apply your Zeyzelf® Twice weekly transdermal patch

- 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 transdermal patches on your body could expose you to an excessive amount of this medicine which could be potentially dangerous.

- Apply **ONE** rectangular transdermal patch together with one adhesive cover to **ONLY ONE** of the possible locations shown in the following diagrams:

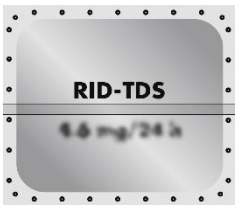
  - left upper arm **or** right upper arm
  - left upper chest **or** right upper chest **(avoid breast)**
  - left upper back **or** right upper back
  - left lower back **or** right lower back

Latest after 4 days take off the previous patches before putting ONE new transdermal patch and one adhesive cover on to ONLY ONE of the following possible locations.

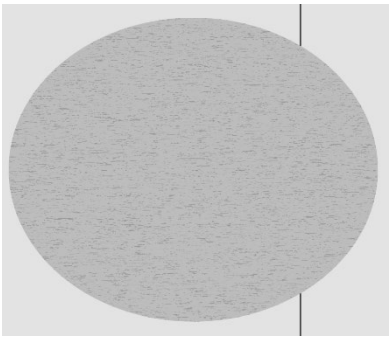


When changing the patches, you must remove the previous patches before you apply the new ones to a different location of skin each time (for example on the right side of your body four days, then on the left side three days, and on your upper body four days, then on your lower body the next three days). Do not apply a new patch to that same skin area Twice within 14 days.

How to apply your Zeyzelf® Twice weekly transdermal patch
Zeyzelf® Twice weekly is for transdermal use.
Zeyzelf® Twice weekly patches consist of two parts:
- one rectangular, translucent, active substance-containing patch (transdermal patch) which is sealed in a sachet and
- one oval, beige, active substance-free fabric patch (adhesive cover) which is also sealed in a sachet. This sachet is bigger than the sachet of the transdermal patch.



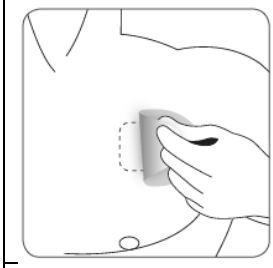
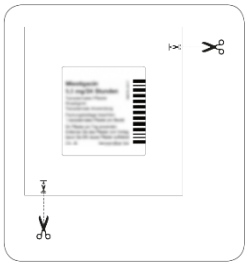
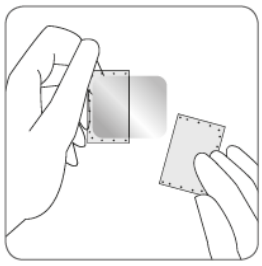
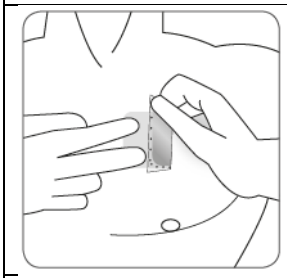
Active substance containing transdermal patch



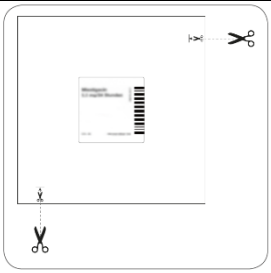
Active substance-free fabric patch (for fixation)

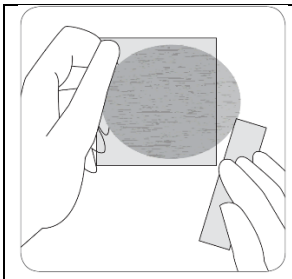
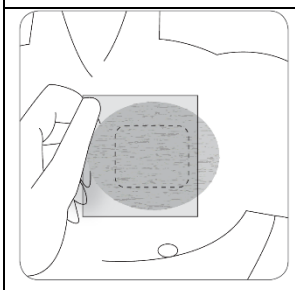
Do not open the sachet or remove a patch until just before you apply it.

The application **always** begins with the **rectangular** transdermal patch.

	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 next picture.
	Each transdermal 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 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 patch. Remove the rectangular, translucent transdermal 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 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)
- urinary tract infection
- anxiety
- depression
- confusion
- headache
- fainting
- stomach problems such as feeling sick (nausea) or being sick (vomiting), diarrhea
- heartburn
- stomach pain
- rash
- allergic reaction where the patch was used, such as blisters or inflamed skin
- feeling tired or weak
- weight loss
- fever

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Uncommon (may affect up to 1 in 100 people)
- problems with your heartbeat such as slow heartbeat
- 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 and trembling hands

Not known (frequency cannot be estimated from the available data)
- the signs of Parkinson's disease get worse – such as tremor, stiffness and shuffling,
- 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
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)
- seeing things that are not there (hallucination)
- trembling
- sleepiness
- rash, itching
- skin reddening
- blisters

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
- feeling restless
- generally feeling unwell
- trembling
- 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 cm^2 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 cm^2 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: siliconised 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: June 2026

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.