

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Rivastigmine Patch Dexcel 4.6 mg/24 h

Rivastigmine Patch Dexcel 9.5 mg/24 h

A patch for use on the skin (Transdermal patch)

Each patch contains:

Rivastigmine Patch Dexcel 4.6 mg/24 h: a 4.6 cm² transdermal patch containing 6.9 mg rivastigmine. The release rate of the medicine is: 4.6 mg in 24 hours.

Rivastigmine Patch Dexcel 9.5 mg/24 h: a 9.2 cm² transdermal patch containing 13.8 mg rivastigmine. The release rate of the medicine is: 9.5 mg in 24 hours.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their illness is similar.

1. What is the medicine intended for?

For the treatment of mild to moderate Alzheimer's dementia (memory problems).

Therapeutic group: Cholinesterase enzyme inhibitors (anticholinesterases).

Rivastigmine belongs to a group of substances called cholinesterase inhibitors. In patients with Alzheimer's dementia, certain nerve cells in the brain die, and cause 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 Patch Dexcel** allows the acetylcholine levels in the brain to be increased, and helps to reduce the symptoms of Alzheimer's disease.

Rivastigmine Patch Dexcel is intended for the treatment of adult patients with mild and moderate dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behavior.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (rivastigmine) or to any of the other ingredients this medicine contains (see section 6).
- You have ever had an allergic reaction to a similar type of medicine (carbamate derivatives).
- You had a skin reaction that spread beyond the patch size, if there was an intense local reaction (such as blisters, increased skin inflammation, swelling) and if this condition did not improve within 48 hours after removal of the patch.

If these conditions apply to you, inform the doctor and do not use **Rivastigmine Patch Dexcel**.

Special warnings regarding the use of the medicine

Before the treatment with Rivastigmine Patch Dexcel, tell the doctor 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

- you have, or have ever had an active stomach ulcer
- you have, or have ever had difficulties in passing urine
- you have, or have ever had seizures
- you have, or have ever had asthma or a severe respiratory disease
- you suffer from trembling
- you have a low body weight
- you have gastrointestinal reactions such as nausea, vomiting and diarrhea. You may become dehydrated (losing too much fluids) if vomiting or diarrhea persist
- you have impaired liver function

In these cases, your doctor may monitor your condition more closely during treatment with the medicine.

If you have not applied **Rivastigmine Patch Dexcel** for more than three days, do not apply the next patch without consulting the attending doctor.

Children and adolescents

Rivastigmine Patch Dexcel is not intended for use in children and adolescents under 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

- Rivastigmine may interfere with anticholinergic medicines, some of which are medicines used to relieve spasms or stomach cramps (such as dicyclomine), for the treatment of Parkinson's disease (such as amantadine) or for the prevention of motion sickness (such as diphenhydramine, scopolamine or meclizine).
- Do not use **Rivastigmine Patch Dexcel** at the same time as metoclopramide (a medicine used to relieve or prevent nausea and vomiting). Using the two medicines together may cause problems such as stiff limbs and trembling hands.
- If you are about to undergo surgery during treatment with **Rivastigmine Patch Dexcel**, inform the doctor about the use of this medicine, as **Rivastigmine Patch Dexcel** may increase the effect of certain muscle relaxants during anesthesia.
- Caution should be exercised when using **Rivastigmine Patch Dexcel** together with beta-blockers (medicines such as atenolol that are used to treat hypertension, angina pectoris, and other heart conditions). Using the two medicines together may cause problems such as slowing of the heartbeat (bradycardia) that may lead to fainting or loss of consciousness.
- Caution should be exercised when using **Rivastigmine Patch Dexcel** together with other medicines that can affect your heart rhythm or the electrical system of the heart (QT prolongation).

Use of the medicine and food

Rivastigmine Patch Dexcel may be used with food and drink.

Use of the medicine and alcohol consumption

Rivastigmine Patch Dexcel may be used with alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or a pharmacist before using the medicine.

There is no information about the use of **Rivastigmine Patch Dexcel** in pregnant women. If you are pregnant, the benefits of **Rivastigmine Patch Dexcel** should be assessed against the possible effects on the fetus. Do not use **Rivastigmine Patch Dexcel** during pregnancy unless its use is absolutely necessary.

Do not breastfeed during treatment with **Rivastigmine Patch Dexcel**. It is not known if rivastigmine is excreted in breast milk.

Driving and using machines

Your doctor will advise you whether your illness allows you to safely drive a vehicle and operate machinery. **Rivastigmine Patch Dexcel** may cause fainting or severe confusion. If you feel faint or confused, do not drive a vehicle, use machines or perform any activity that requires alertness.

3. How to use the medicine

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

Important:

- **Remove the previous patch before applying one new patch.**
- **Only one patch per day.**
- **Do not cut the patch into pieces.**
- **Press the patch firmly for at least 30 seconds with the palm of the hand.**
- **For external use only.**

How to start the treatment?

Your doctor will tell you which **Rivastigmine Patch Dexcel** is most suitable for you.

- Treatment usually starts with **Rivastigmine Patch Dexcel 4.6 mg/24 h**.
 - The usual recommended daily dose is **Rivastigmine Patch Dexcel 9.5 mg/24 h**. If well tolerated, the doctor may increase the dosage to 13.3 mg/24 hours (a dosage of 13.3 mg/24 hours cannot be achieved with **Rivastigmine Patch Dexcel**. In cases where this dosage is to be used, use other Rivastigmine products, which have transdermal patches in a dosage of 13.3 mg/24 hours).
 - Use only one patch at a time and replace the patch with a new one after 24 hours.
- During the course of treatment, the doctor may adjust the dose to suit your individual needs.

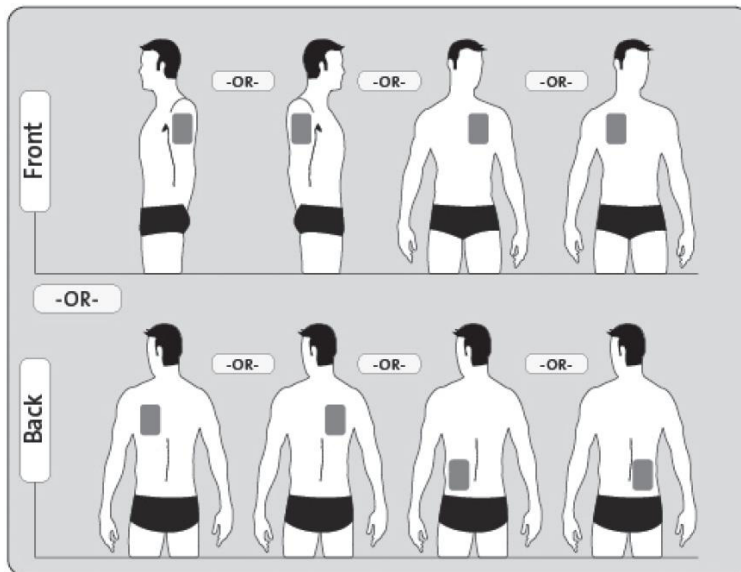
Do not exceed the recommended dose.

If you have not applied **Rivastigmine Patch Dexcel** for more than three days, do not apply the next patch before consulting your doctor. Treatment with the patch can be resumed at the same dose if the treatment was not interrupted for more than three days. Otherwise, the doctor will restart the treatment with **Rivastigmine Patch Dexcel 4.6 mg/24 h**.

Where to apply Rivastigmine Patch Dexcel?

- Before applying a patch, make sure the skin is clean, dry and hairless, free of any powder, oil, moisturizer or lotion that could keep the patch from sticking to the skin properly, free of cuts, rashes and/or irritations.
- **Carefully remove an existing patch before putting on a new patch.** If multiple patches are applied to your body, your body may be exposed to an excessive amount of the medicine, a situation that can be dangerous.
- Apply **only one** patch per day, to **only one** of the possible locations shown in the following illustrations:
 - Left upper arm **or** right upper arm
 - Upper left side of the chest **or** upper right side of the chest (**avoid applying the patch to the breast**)
 - Upper left side of the back **or** upper right side of the back
 - Left side of the lower back **or** right side of the lower back

Every 24 hours, remove the existing patch before putting one new patch to only one of the following possible locations:

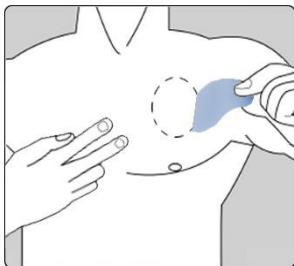


When changing the patch, you must remove the previous day's patch before you apply the new patch, each time to a different location on the skin (for example on the right side of the body one day and the left side the next day, on the upper part of the body one day and the lower part of the body the next day).

Do not apply a new patch in the exact same area twice within 14 days.

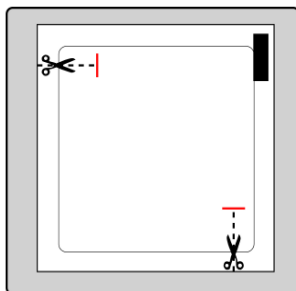
How to apply Rivastigmine Patch Dexcel?

The patch is thin, light brown and sticks to the skin. Each patch is packed in a closed sachet that protects it until you are ready to apply it. Do not open the sachet or take out the patch except right before applying it.



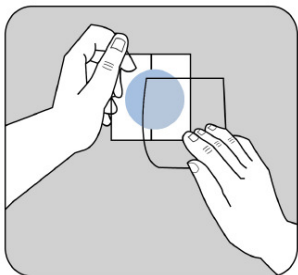
Carefully remove the existing patch before applying a new patch.

Patients starting treatment for the first time and patients restarting treatment after treatment interruption, please begin with the second illustration.

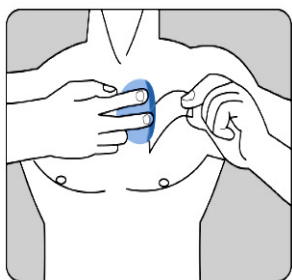


Each patch is sealed in a closed sachet that protects it.

Open the sachet only when you are ready to apply the patch. Cut the sachet at both scissors marks, but not beyond the indicated line. To open, tear the sachet. 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 layer from the upper side of the patch that is light brown and discard the cover. There is a protective layer on the sticky side of the patch. Remove one side of the protective layer 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 area, on the upper part of the arm or on the chest and then remove the second side of the protective layer.



Afterwards, press the patch firmly **for at least 30 seconds** using the palm of the hand to make sure that the edges stick well.

If it helps you, you can write for example the day of the week on the patch with a thin ballpoint pen.

Leave the patch in place continuously until it is time to replace it with a new patch. You may wish to experiment with different locations when applying a new patch to find the places that are most comfortable for you and where clothing will not rub against the patch.

How to remove Rivastigmine Patch Dexcel?

Gently and slowly pull at one edge of **Rivastigmine Patch Dexcel** to remove it from the skin. In case adhesive residue remains on the skin, gently wet the area with warm water and mild soap or use baby oil to remove it. Do not use alcohol or other dissolving liquids (nail polish remover or other solvents).

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

Can Rivastigmine Patch Dexcel be used when bathing, swimming or during exposure to 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, sauna, solarium) for long periods of time.

What to do if the patch falls off?

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

When and for how long to apply Rivastigmine Patch Dexcel?

- To benefit from the treatment, you must apply a new patch every day, it is preferable to replace the patch at the same time each day.
- Only wear one patch at a time and replace it with a new patch after 24 hours.

If you have accidentally applied more Rivastigmine Patch Dexcel than required

If you accidentally apply more than one patch, remove all the patches from your skin and then inform the attending doctor that you have accidentally applied more than one patch. You may require medical supervision. Some people who have accidentally taken too much Rivastigmine have experienced nausea, vomiting, diarrhea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur.

If you have used an overdose or if a child has accidentally swallowed the medicine or applied a patch on his body, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to apply Rivastigmine Patch Dexcel

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

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stopped using Rivastigmine Patch Dexcel

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

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like any medicine, the use of **Rivastigmine Patch Dexcel** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The frequency of side effects is higher when starting the treatment or when increasing the dosage of the medicine. In most cases, the side effects will gradually disappear, as the body gets used to the medicine.

Remove the patch and inform the attending doctor immediately, if you experience any of the following side effects which could become serious:

Common side effects (effects that occur in 1-10 out of 100 users):

- Loss of appetite
- Feeling dizzy
- Feeling agitated or sleepy
- Urinary incontinence (inability to retain adequate urine)

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Problems with your heartbeat such as a slow heartbeat
- Seeing things that do not really exist (hallucinations)
- Stomach ulcer
- Dehydration (losing too much fluids)

- Hyperactivity (high level of activity, restlessness)
- Aggression

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Falls

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Stiff arms or legs
- Trembling hands

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Allergic reaction where the patch was applied, such as blisters or inflamed skin
- Worsening of Parkinson's disease symptoms – such as tremor, stiffness and shuffling
- Inflammation of the pancreas – the symptoms include serious upper stomach pain, often accompanied by nausea or vomiting
- Fast or irregular heartbeat
- High blood pressure
- Fits (seizures)
- Liver disorders (yellow skin, yellowing of the whites of the eyes, abnormally dark urine or unexplained nausea, vomiting, tiredness and loss of appetite)
- Changes in results of tests which show how well the liver is functioning
- Feeling restless
- Nightmares

Remove the patch and refer to your doctor immediately, if you experience any of the above side effects.

Additional side effects reported for rivastigmine capsules or rivastigmine solution and which may occur with the patches:

Common side effects (effects that occur in 1-10 out of 100 users):

- Excess saliva
- Loss of appetite
- Feeling restless
- Generally feeling unwell
- Trembling or feeling confused
- Excessive sweating

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Irregular heart rate (e.g., fast heart rate)
- Difficulty sleeping
- Accidental falls

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Fits (seizures)
- Ulcer in the intestine
- Chest pain that may be caused by heart spasm

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- High blood pressure
- Inflammation of the pancreas – the symptoms include serious upper stomach pain, usually accompanied by nausea or vomiting
- Bleeding in the gut – shows as blood in stools or in vomit

- Seeing things that do not exist (hallucinations)
- Some of the patients who suffered from severe vomiting have had tearing of the esophagus that connects the mouth to the stomach

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not which is not listed in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C. Store in the original package.
- Keep the patch in its sachet until using it.
- Do not use the patch if it is damaged or if there are signs of opening.
- After removing the patch, fold it in half with the sticky sides facing inward and press and tighten them together. Return the used patch to its sachet and dispose of it in such a way that children will not be able to touch it. Do not touch your eyes with your fingers, wash your hands with soap and water after removing the patch. Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Polyester film, fluoropolymer-coated, polyethylene/thermoplastic resin/aluminum coated polyester film, poly [(2-ethylhexyl)acrylate, vinylacetate], high molecular weight polyisobutene, paraffin light liquid, medium molecular weight polyisobutene, silica colloidal anhydrous, orange printing color.

What the medicine looks like and what the package contains:

Round patch. The outer layer is light brown with the marking:

"RIV-TDS 4.6 mg/24 h" for **Rivastigmine Patch Dexcel 4.6 mg/24 h**.

"RIV-TDS 9.5 mg/24 h" for **Rivastigmine Patch Dexcel 9.5 mg/24 h**.

Each patch is packed in a closed sachet. Each package contains 30 sachets.

Manufacturer name and address: Luye Pharma AG, Miesbach, Germany

Revised in August 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Rivastigmine Patch Dexcel 4.6 mg/24 h: 158-87-34462-00

Rivastigmine Patch Dexcel 9.5 mg/24 h: 158-88-34452-00

Registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel