

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

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

Rivastigmine Patch Dexcel 4.6mg /24h Rivastigmine Patch Dexcel 9.5mg /24h

Transdermal patch

Each patch contains:

Rivastigmine Patch Dexcel 4.6 mg/24 hours: 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 hours: 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 this 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 for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

For the treatment of mild to moderate Alzheimer memory-dementia 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 increase, and aids in reducing 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 the 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 the 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 size of the patch, if there was an intense local reaction (e.g., 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 previously had an irregular or slow heartbeat
- you have, or have previously had an active stomach ulcer
- you have, or have previously had difficulties in passing urine
- you have, or have previously had seizures
- you have, or have previously had asthma or a severe respiratory disease
- you suffer from trembling
- you have a low body weight
- you have digestive system reactions such as nausea, vomiting and diarrhea. You may become dehydrated (due to loss of 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 used **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. Do not use **Rivastigmine Patch Dexcel** at the same time as other medicines with an effect similar to **Rivastigmine Patch Dexcel**.

- Rivastigmine may interfere with anticholinergic medicines, some of which are medicines used to relieve spasms or stomach cramps (e.g., dicyclomine), for the treatment of Parkinson's disease (e.g., amantadine) or for the prevention of motion sickness (such as diphenhydramine, scopolamine or medizine).
- 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 slow heartbeat (bradycardia) that may lead to fainting or loss of consciousness.

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 pharmacist before using this 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 considered 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 disease allows you to drive a car and operate machines. **Rivastigmine Patch Dexcel** may cause fainting or serious confusion.

If you feel faint or confused, do not drive a car or operate machines. Avoid any activity that requires alertness.

3. How to use this medicine

Always use this 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.

Initiation of treatment and supervision of the treatment will be carried out by a doctor experienced in diagnosis and treatment of Alzheimer's dementia. A diagnosis should be performed according to current guidelines. As with any treatment initiation for patients with dementia, treatment with rivastigmine should only be started if there is an available caretaker for regular administration and monitoring of the treatment.

Important:

- Remove the previous patch before applying one new patch.**
- Use only one patch each day.**
- Do not cut the patch into pieces.**
- When applying the patch press firmly for at least 30 seconds with the palm of the hand.**
- Do not exceed the recommended dose.**
- 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 hours**.
 - The usual recommended daily dose is **Rivastigmine Patch Dexcel 9.5 mg/24 hours**. 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 at a dosage of 13.3 mg/24 hours).
 - Use only one patch each time and replace the patch with a new one after 24 hours.
- During treatment the doctor may adjust the dose so it will suit your individual needs.

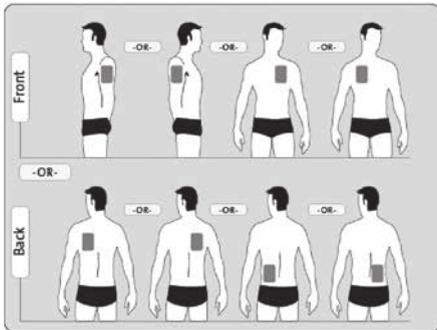
If you have not used **Rivastigmine Patch Dexcel** for more than three days, do not apply the next patch before consulting your doctor.

Treatment with the patch can be resumed at the same dose, if the treatment has not been stopped for more than three days. Otherwise, the doctor will resume the treatment with **Rivastigmine Patch Dexcel 4.6 mg/24 hours**.

Where to apply Rivastigmine Patch Dexcel?

- Before applying **Rivastigmine Patch Dexcel** make sure the skin is: clean, dry and hairless, free of any powder, oil, moisturizer or lotion that may keep the patch from adhering to the skin properly, skin with no cuts, rashes and/or irritations.
- Carefully remove the existing patch before applying a new patch.** If several patches are applied to your body, your body may be exposed to an excessive amount of the medicine, a situation that may be dangerous.
- Apply **only one** patch per day, to **only one** of the following areas that are shown in the following illustrations:
 - The upper part of the left or right arm
 - upper left side of the chest or upper right side of the chest (**avoid applying 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 applying a new patch to one of the following locations only:



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 same skin area twice within 14 days.

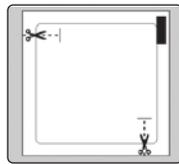
How to apply Rivastigmine Patch Dexcel?

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.

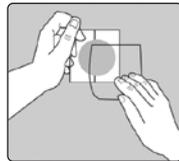


Carefully remove the existing patch before applying a new patch.

Patients starting the treatment for the first time and patients restarting treatment after a break in the treatment, should start with the second illustration.



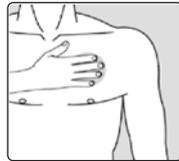
Each patch is sealed in a closed sachet that protects it. Open the sachet only when you are ready to use the patch. Cut the sachet at the two scissors marks, but not beyond the indicated line. To open, tear the sachet. Do not cut along the entire length of the sachet in order to avoid causing damage to the patch. Take the patch out of the sachet.



Remove the cover layer from the upper side of the patch that is light brown and dispose of the cover. There is a protective layer on the adhesive side of the patch. Remove one side of the protective layer, 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 will help you remember, it is possible to 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 try different places to apply the new patch to find the most comfortable places and the places where the clothes 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 the adhesive residue. 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 redness appears in the eyes after handling the patch, immediately rinse the eyes with plenty of water. If the symptoms do not pass seek medical advice.

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 your medicine, you should use a new patch every day, it is preferable to change the patch at the same time each day.
- Wear only one patch at a time and replace it with a new patch after 24 hours.

If you have accidentally used more Rivastigmine Patch Dexcel than necessary

If you accidentally used more than one patch, remove all the patches from your skin and then inform the attending doctor that you accidentally used 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 a child accidentally applied **Rivastigmine Patch Dexcel**, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine.

If you forget to apply Rivastigmine Patch Dexcel

If you find that you have forgotten to use **Rivastigmine Patch Dexcel**, apply a new patch immediately. The next patch can be used 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.

If you stopped using Rivastigmine Patch Dexcel

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

Refer to and tell the doctor or pharmacist if you have stopped 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 adapts to the medicine.

Remove the patch and inform the attending doctor immediately, if you experience one or more of these side effects which may be serious:

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

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

Uncommon side effects (effects that appear 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 fluid)
- Hyperactivity (high level of activity, restlessness)
- Aggression

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

- Falls

Very rare side effects (effects that appear in less than one in 10,000 users):

- Stiff hands 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 and inflamed skin
- Worsening of the signs of Parkinson's disease – such as tremor, stiffness and shuffling
- Inflammation of the pancreas – the symptoms include serious upper stomach pain, usually accompanied by nausea and vomiting
- Fast and irregular heartbeat
- High blood pressure
- Fits
- 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 test results that indicate 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 and which may occur with patches:

Common side effects (effects which appear in 1-10 out of 100 users):

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

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

- Irregular heart rate (e.g., fast heart rate)
- Sleeping difficulties
- Accidental falls

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

- Fits
- An ulcer in the intestine
- Chest pain that may be caused by heart spasms

Very rare side effects (effects that appear in less than one in 10,000 users):

- High blood pressure
- Inflammation of the pancreas – the symptoms include serious upper stomach pain, usually accompanied by nausea and vomiting
- Bleeding in the digestive system – blood in stools or vomit
- Seeing things that do not exist (hallucinations)
- Some of the patients who suffered from severe vomiting had a tear of the esophagus that connects the mouth to the stomach

If a side effect appears, 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 via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following 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 at a temperature below 25°C. Store in the original package.
- Keep the patch in its sachet until you use 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. Ask the pharmacist how to dispose of used patches or those that are no longer needed. It is advisable to discard used patches in their original package.

6. Additional information

In addition to the active ingredient, this 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/24h" for **Rivastigmine Patch Dexcel 4.6mg/24h**.
"RIV-TDS 9.5 mg/24h" for **Rivastigmine Patch Dexcel 9.5mg/24h**.
Each patch is packed in a closed sachet. Each package contains 30 sachets.

Manufacturer: Luye Pharma AG, Miesbach, Germany

Revised in February 2021 according to MOH guidelines.

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

Rivastigmine Patch Dexcel 4.6mg/ 24hours:

158-87-34462-00

Rivastigmine Patch Dexcel 9.5mg/ 24hours:

158-88-34452-00

Rivastigmine Patch Dexcel PIL PB0221-10

Registration holder: **Dexcel® Ltd.**

1 Dexcel St., Or Akiva 3060000, Israel