

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

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

**Rivastigmine Dexcel 1.5, 3, 4.5, 6 mg, capsules**

Each capsule contains Rivastigmine (as hydrogen tartrate) 1.5, 3, 4.5 or 6 mg respectively. 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 patients with mild to moderately severe dementia of the Alzheimer's type, also called Alzheimer's disease.

For the symptomatic treatment of mild to moderately severe Alzheimer's dementia.

For the symptomatic treatment of mild to moderately severe dementia associated with Parkinson's disease.

Rivastigmine belongs to a group of substances called cholinesterase inhibitors. In patients with dementia of Alzheimer's disease or Parkinson's disease, 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 Dexcel** allows levels of acetylcholine to be increased in the brain, and helps to reduce the symptoms of Alzheimer's disease and dementia associated with Parkinson's disease.

**Rivastigmine Dexcel** is intended 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 behavior. The capsules can also be used to treat dementia in adult patients with Parkinson's disease.

**Therapeutic group:** cholinesterase enzyme inhibitors.

**2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (rivastigmine), to carbamate derivatives or to any of the other ingredients this medicine contains (see section 6).
- You have had a skin reaction while using a rivastigmine patch, spreading beyond the rivastigmine patch size, if there was a more intense local reaction (e.g., blisters, increased skin inflammation, swelling) and if this condition did not improve within 48 hours after removing the patch.

If these conditions apply to you, tell the doctor and do not take **Rivastigmine Dexcel**.

**Special warnings regarding the use of the medicine**

**Before the treatment with Rivastigmine Dexcel, tell the doctor if:**

- You have, or have ever had a heart condition such as an irregular or a 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 have, or have ever had impaired kidney function.
  - You have, or have ever had impaired liver function.
  - 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 fluid), if the vomiting or diarrhea persist.
- If any of these apply to you, the doctor may need to monitor you more closely during treatment with the medicine.

If you have not taken **Rivastigmine Dexcel** for more than three days, do not take the next dose until you have consulted your doctor.

### **Children and adolescents**

The use of **Rivastigmine Dexcel** is not relevant for the treatment of Alzheimer' disease in the pediatric population.

### **Drug interactions**

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

Do not take **Rivastigmine Dexcel** at the same time as medicines with a similar effect to **Rivastigmine Dexcel**.

Rivastigmine may interfere with anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness).

Do not take **Rivastigmine Dexcel** together with metoclopramide (a medicine used to relieve or prevent nausea and vomiting). Taking the two medicines together may cause problems, such as stiff limbs and trembling hands.

If you are about to undergo surgery while taking **Rivastigmine Dexcel**, inform the doctor before you are given any anesthetics because **Rivastigmine Dexcel** can increase the effect of certain muscle relaxants during anesthesia.

Caution should be exercised when taking **Rivastigmine Dexcel** together with beta-blockers (medicines such as: atenolol used to treat hypertension, angina pectoris and other heart conditions). Taking the two medicines together may cause problems such as slow heartbeat (bradycardia) that leads to fainting or loss of consciousness.

Caution should be exercised when **Rivastigmine Dexcel** is taken 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**

Take **Rivastigmine Dexcel** twice a day, once with breakfast and once with dinner.

### **Pregnancy, breastfeeding and fertility**

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

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

It is not known whether rivastigmine is excreted in breast milk, therefore do not breastfeed during treatment with **Rivastigmine Dexcel**.

### **Driving and using machines**

The doctor will tell you whether your illness allows you to drive a car and safely use machines. **Rivastigmine Dexcel** may cause dizziness and somnolence, mainly at the start of treatment or when increasing the dosage. If you feel dizzy or sleepy, do not drive, use machines or engage in any activity that requires concentration.

### **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.

#### **How to start treatment?**

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

- The treatment usually starts with a low dose.
- The doctor will gradually increase your dose depending on your response to treatment.
- The highest dose that can be taken is 6 mg twice a day.

During the treatment the doctor will regularly check if the medicine is working for you. The doctor will also monitor your weight while you are taking the medicine.

If you have not taken **Rivastigmine Dexcel** for more than three days, do not take the next dose until you have consulted your doctor.

#### **Do not exceed the recommended dose.**

#### **Taking this medicine**

- Tell your caregiver that you are taking **Rivastigmine Dexcel**.
- To benefit from the medicine, take it every day.

#### **Method of administration**

- Take **Rivastigmine Dexcel** twice a day, in the morning and in the evening, with food.
- Do not chew! Swallow the capsules whole with a drink.
- Do not open the capsules and do not crush them.

#### **If you have accidentally taken a higher dosage**

If you have accidentally taken a higher dosage of **Rivastigmine Dexcel** than required, inform your doctor. You may need medical supervision.

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

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 forgot to take the medicine**

If you forgot to take the **Rivastigmine Dexcel** dose at the designated time, take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.

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

**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 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 the side effects may be higher at the beginning of treatment or when increasing the dose of the medicine. Usually the side effects will gradually disappear, as the body gets used to the medicine.

**Very common side effects** (effects that occur in more than 1 in 10 users):

- Dizziness
- Loss of appetite
- Stomach problems, such as nausea or vomiting, diarrhea

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

- Anxiety
- Sweating
- Headache
- Heartburn
- Weight loss
- Stomach pain
- Feeling agitated
- Feeling tired or weak
- Generally feeling unwell
- Trembling or feeling confused
- Decreased appetite
- Nightmares

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

- Depression
- Difficulty in sleeping
- Fainting or accidentally falling
- Changes in liver function

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

- Chest pain
- Rash, itching
- Seizures
- Ulcers in the stomach or intestine

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

- High blood pressure
- Urinary tract infection
- Seeing things that are not there (hallucinations)
- Heartbeat problems such as fast or slow heartbeat
- Bleeding in the gut – shows as blood in stools or when vomiting
- Inflammation of the pancreas - symptoms include severe upper stomach pain, usually accompanied by nausea or vomiting

- Worsening of Parkinson's disease symptoms or development of similar symptoms such as stiff muscles, difficulty in carrying out movements

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

- Severe vomiting that can cause tearing of the esophagus, a tube that connects the mouth to the stomach
- Dehydration (losing too much fluids)
- 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)
- Aggression, feeling restless
- Uneven heartbeat

**Patients with dementia associated with Parkinson's disease:**

These patients have some side effects more often. They also have some additional side effects:

**Very common side effects** (effects that occur in more than 1 in 10 users):

- Trembling
- Fainting
- Accidentally falling

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

- Anxiety
- Feeling restless
- Slow heartbeat
- Difficulty in sleeping
- Too much saliva and dehydration
- Unusually slow movements or movements you cannot control
- Worsening of Parkinson's disease symptoms or development of similar symptoms such as stiff muscles, difficulty in carrying out movements and muscle weakness

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

- Uneven heartbeat and poor control of movements

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

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

- Fever
- Severe confusion
- Urinary incontinence (inability to retain adequate urine)

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

- Hyperactivity (high level of activity, restlessness)

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

- Allergic reaction where the patch was used, such as blisters or skin inflammation

If you experience one of these side effects, refer to your doctor, you may need medical attention.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned 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](http://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.
- 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:**

Microcrystalline cellulose, gelatin, hypromellose, silica colloidal anhydrous, magnesium stearate, titanium dioxide (E171), yellow iron oxide (E172), purified water, printing ink.

**Rivastigmine Dexcel 3, 4.5, 6 mg** also contain red iron oxide (E172).

**What the medicine looks like and what the package contains:**

**Rivastigmine Dexcel 1.5 mg:** yellow hard gelatin capsules imprinted with "RIVA 1.5mg" in black on the body.

**Rivastigmine Dexcel 3 mg:** light orange hard gelatin capsules imprinted with "RIVA 3mg" in black on the body.

**Rivastigmine Dexcel 4.5 mg:** caramel hard gelatin capsules imprinted with "RIVA 4.5mg" in black on the body.

**Rivastigmine Dexcel 6 mg:** light orange/caramel hard gelatin capsules imprinted with "RIVA 6mg" in black on the body.

The capsules contain a white to off-white powder.

Approved package sizes: 14, 28, 56, 84, 112 capsules. Not all package sizes may be marketed.

**Manufacturer name and address:** Geneparm S.A., 18th Km Marathonos Avenue, Pallini Attikis, 15351, Greece.

Revised in July 2023 according to MOH guidelines.

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

**Rivastigmine Dexcel 1.5 mg:** 152-77-33949-00

**Rivastigmine Dexcel 3 mg:** 152-78-33950-00

**Rivastigmine Dexcel 4.5 mg:** 152-79-33951-00

**Rivastigmine Dexcel 6 mg:** 152-80-33952-00

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