

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**RISTIDIC 1,5 mg, capsule, hard**  
**RISTIDIC 3,0 mg, capsule, hard**  
**RISTIDIC 4,5 mg, capsule, hard**  
**RISTIDIC 6,0 mg, capsule, hard**

Rivastigmine

**Read all of this leaflet carefully before you start taking 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 <PRODUCT NAME> is and what it is used for
2. What you need to know before you take <PRODUCT NAME>
3. How to take <PRODUCT NAME>
4. Possible side effects
5. How to store <PRODUCT NAME>
6. Contents of the pack and other information

### **1. What <PRODUCT NAME> is and what it is used for**

The active substance of <PRODUCT NAME> is rivastigmine.

Rivastigmine belongs to a class of substances called cholinesterase inhibitors.

In patients with Alzheimer's dementia or dementia due to 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, <PRODUCT NAME> allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's disease and dementia associated with Parkinson's disease.

<PRODUCT NAME> 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. The capsules can also be used for the treatment of dementia in adult patients with Parkinson's disease.

### **2. What you need to know before you take <PRODUCT NAME>**

#### **Do not take <PRODUCT NAME>**

- if you are allergic to rivastigmine (the active substance in <PRODUCT NAME> or any of the other ingredients of this medicine (listed in section 6)).
- 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 take <PRODUCT NAME>.

### **Warnings and precautions**

Talk to your doctor before taking <PRODUCT NAME>:

- 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 severe respiratory disease.
- if you have, or have ever had impaired kidney function.
- if you have, or have ever had, impaired liver function.
- 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 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 taken <PRODUCT NAME> for more than three days, do not take the next dose until you have talked to your doctor.

### **Children and adolescents**

There is no relevant use of <PRODUCT NAME> in the paediatric population in the treatment of Alzheimer's disease.

### **Other medicines and <PRODUCT NAME>**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<PRODUCT NAME> should not be given at the same time as other medicines with similar effects to <PRODUCT NAME>. <PRODUCT NAME> might interfere with anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness).

<PRODUCT NAME> 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 taking <PRODUCT NAME>, tell your doctor before you are given any anaesthetics, because <PRODUCT NAME> may exaggerate the effects of some muscle relaxants during anaesthesia.

Caution when <PRODUCT NAME> is taken 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 <PRODUCT NAME> 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 <PRODUCT NAME> must be assessed against the possible effects on your unborn child. <PRODUCT NAME> should not be used during pregnancy unless clearly necessary.

You should not breast-feed during treatment with <PRODUCT NAME>.

### **Driving and using machines**

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. <PRODUCT NAME> may cause dizziness and somnolence, mainly at the start of treatment or when increasing the dose. If you feel dizzy or sleepy, do not drive, use machines or perform any tasks that require your attention.

## **3. How to take <PRODUCT NAME>**

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

### **How to start treatment**

Your doctor will tell you what dose of <PRODUCT NAME> to take.

- Treatment usually starts with a low dose.
- Your doctor will slowly increase your dose depending on how you respond to treatment.
- The highest dose that should be taken is 6.0 mg twice a day.

Your doctor will regularly check if the medicine is working for you. Your doctor will also monitor your weight whilst you are taking this medicine.

If you have not taken <PRODUCT NAME> for more than three days, do not take the next dose until you have talked to your doctor.

### **Taking this medicine**

- Tell your caregiver that you are taking <PRODUCT NAME>.
- To benefit from your medicine, take it every day.
- Take <PRODUCT NAME> twice a day, in the morning and evening, with food.
- Swallow the capsules whole with a drink.
- Do not open or crush the capsules.

### **If you take more <PRODUCT NAME> than you should**

If you accidentally take more <PRODUCT NAME> than you should, inform your doctor. You may require medical attention. Some people who have accidentally taken too much <PRODUCT NAME> 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 take <PRODUCT NAME>**

If you find you have forgotten to take your dose of <PRODUCT NAME>, wait and take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

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.

##### **Very common** (may affect more than 1 in 10 people)

- Feeling dizzy
- Loss of appetite
- Stomach problems such as feeling sick (nausea) or being sick (vomiting), diarrhoea

##### **Common** (may affect up to 1 in 10 people)

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

##### **Uncommon** (may affect up to 1 in 100 people)

- Depression
- Difficulty in sleeping
- Fainting or accidentally falling
- Changes in how well your liver is working

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

- Chest pain
- Rash, itching
- Fits (seizures)
- Ulcers in your stomach or intestine

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

- High blood pressure
- Urinary tract infection
- Seeing things that are not there (hallucinations)
- Problems with your heartbeat such as fast or slow heartbeat
- Bleeding in the gut – shows as blood in stools or when being sick
- Inflammation of the pancreas – the signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- The signs of Parkinson's disease get worse or getting similar signs – such as stiff muscles, difficulty in carrying out movements

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

- Being violently sick (vomiting) that can cause tearing of the tube that connects your mouth with your stomach (oesophagus)
- Dehydration (losing too much fluid)
- 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
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

**Patients with dementia and Parkinson's disease**

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

**Very common** (may affect more than 1 in 10 people)

- Trembling
- Accidentally falling

**Common** (may affect up to 1 in 10 people)

- Anxiety
- Feeling restless
- Slow and fast heartbeat
- Difficulty in sleeping
- Too much saliva and dehydration
- Unusually slow movements or movements you cannot control
- The signs of Parkinson's disease get worse or getting similar signs – such as stiff muscles, difficulty in carrying out movements and muscle weakness
- Seeing things that are not there (hallucinations)
- Depression
- High blood pressure

**Uncommon** (may affect up to 1 in 100 people)

- Uneven heartbeat and poor control of movements
- Low blood pressure

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

- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)
- Skin rash

**Other side effects seen with <PRODUCT NAME> transdermal patches and which may occur with the hard capsules:**

**Common** (may affect up to 1 in 10 people)

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

**Uncommon** (may affect up to 1 in 100 people)

- Hyperactivity (high level of activity, restlessness)

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

- Allergic reaction where the patch was used, such as blisters or skin inflammation.
- If you get any of these side effects, contact your doctor as you may need medical assistance.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store <PRODUCT NAME>**

- 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 after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storing conditions.
- 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 <PRODUCT NAME> contains**

Capsule content:

- Active substance: rivastigmine hydrogen tartrate.
- The other ingredients are: Hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose (E460), Silica colloidal anhydrous (E551),

Capsule shell:

- gelatin (E441), yellow iron oxide (E172), titanium dioxide (E171), iron oxide red , E172 (only for the 3.0, 4.5 & 6.0 mg capsule shells) and printing ink.

Printing ink contains shellac, propylene glycol, concentrated ammonia solution, iron oxide black and potassium Hydroxide

Each capsule contains 1.5 mg of rivastigmine.

Each capsule contains 3.0 mg of rivastigmine.

Each capsule contains 4.5 mg of rivastigmine.

Each capsule contains 6.0 mg of rivastigmine.

#### **What <PRODUCT NAME> looks like and contents of the pack**

<PRODUCT NAME> 1.5 mg hard capsules, are yellow/yellow hard gelatine capsule imprinted with “RIVA 1.5mg” on body with black ink containing white to off-white granular powder of 1.5 mg of rivastigmine.

<PRODUCT NAME> 3.0 mg hard capsules, are light orange/ light orange hard gelatine capsule imprinted with “RIVA 3mg” on body with black ink containing white to off-white granular powder of 3.0 mg of rivastigmine

<PRODUCT NAME> 4.5 mg hard capsules, are caramel/caramel hard gelatine capsule imprinted with “RIVA 4.5mg” on body with black ink containing white to off-white granular powder of 4.5 mg of rivastigmine.

<PRODUCT NAME> 6.0 mg hard capsules, are light orange/caramel hard gelatine capsule imprinted with “RIVA 6mg” on body with black ink containing white to off-white granular powder of 6.0 mg of rivastigmine.

They are packed in blisters available in three different pack sizes (28, 56 or 112 capsules)  
Not all pack sizes may be marketed

### **Marketing Authorisation Holder and Manufacturer**

Houder van de vergunning voor het in de handel brengen:

Bausch Health Ireland Limited  
3013 Lake Drive  
Citywest Business Campus  
Dublin 24, D24PPT3  
Ireland

Fabrikanten:

Genepfarm S.A.  
18th km Marathonos Avenue,  
153 51 Pallini Attiki  
Griekenland

Bausch Health Poland sp. z.o.o.  
21 Kosztowska Str.,  
41-409 Mysłowice  
Polen

#### **In het register ingeschreven onder:**

RISTIDIC 1,5 mg, capsule, hard	RVG 103326
RISTIDIC 3,0 mg, capsule, hard	RVG 103327
RISTIDIC 4,5 mg, capsule, hard	RVG 103328
RISTIDIC 6,0 mg, capsule, hard	RVG 103329

**This medicinal product is authorized in the Member States of the EEA under the following names:**

***NL/H/1542/001-004/DC***

The Netherlands:	<b>RISTIDIC 1.5 / 3 / 4.5 / 6 mg Capsule, hard</b>
Poland:	<b>RISTIDIC</b>
Slovak Republik:	<b>RISTIDIC 1.5 / 3 / 4.5 / 6 / mg tvrdé kapsule</b>

**Deze bijsluiter is voor het laatst goedgekeurd in december 2025.**