PACKAGE LEAFLET: INFORMATION FOR THE USER

Rivastigmine DEMO 1.5 mg hard capsules
Rivastigmine DEMO 3.0 mg hard capsules,
Rivastigmine DEMO 4.5 mg hard capsules
Rivastigmine DEMO 6.0 mg hard capsules
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 Rivastigmine DEMO is and what it is used for

The active substance of Rivastigmine DEMO 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, Rivastigmine 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.

Rivastigmine DEMO 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 behavior. The capsules and oral solution 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 Rivastigmine DEMO

Do not take Rivastigmine DEMO
- if you are allergic to rivastigmine (the active substance in Rivastigmine DEMO) 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 Rivastigmine DEMO.

Warnings and precautions

Talk to your doctor before taking Rivastigmine DEMO:

- if you have, or have ever had, irregular or slow heartbeat.
- 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 diarrhea. You may become dehydrated (losing too much fluid) if vomiting or diarrhea 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 Rivastigmine DEMO 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 Rivastigmine DEMO in the paediatric population in the treatment of Alzheimer's disease.

Other medicines and Rivastigmine DEMO

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

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

Rivastigmine DEMO 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 such as stiff limbs and trembling hands.

If you have to undergo surgery whilst taking Rivastigmine, tell your doctor before you are given any anaesthetics, because Rivastigmine may exaggerate the effects of some muscle relaxants during anaesthesia.

Caution when Rivastigmine DEMO 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.

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 Rivastigmine DEMO must be assessed against the possible effects on your unborn child. Rivastigmine DEMO should not be used during pregnancy unless clearly necessary.

You should not breast-feed during treatment with Rivastigmine DEMO.

Driving and using machines
Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely.
Rivastigmine 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 Rivastigmine DEMO

Always take 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 what dose of r Rivastigmine DEMO 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 Rivastigmine 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 Rivastigmine.
- To benefit from your medicine, take it every day.
- Take Rivastigmine 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 Rivastigmine DEMO than you should
If you accidentally take more Rivastigmine than you should, inform your doctor. 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 take Rivastigmine DEMO If you find you have forgotten to take your dose of Rivastigmine 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), diarrhea

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

Uncommon (may affect up to 1 to 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

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
- Fainting
- 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

Uncommon (may affect up to 1 in 100 people)
- Uneven heartbeat and poor control of movements

Other side effects 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)

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 Nederlands Bijwerkingen Centrum Lareb Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rivastigmine DEMO

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 blister and the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage 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 Rivastigmine DEMO 1.5 mg capsules, hard contains

- The active substance is rivastigmine. Each capsule contains rivastigmine hydrogen tartrate corresponding to rivastigmine 1.5 mg.
- The other ingredients in the capsules are
  Capsule contents: hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose (E460) and colloidal anhydrous silica (E551).
  Capsule shell: gelatin (E441), yellow iron oxide (E172) and titanium dioxide (E171). The printing ink contains shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Rivastigmine DEMO 3.0 mg capsules, hard contains

- The active substance is rivastigmine. Each capsule contains rivastigmine hydrogen tartrate corresponding to rivastigmine 3.0 mg.
- The other ingredients in the capsules are
  Capsule contents: hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose (E460) and colloidal anhydrous silica (E551).
  Capsule shell: gelatin (E441), yellow iron oxide (E172), red iron oxide (E172) and titanium dioxide (E171). The printing ink contains shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Rivastigmine DEMO 4.5 mg capsules, hard contains

- The active substance is rivastigmine. Each capsule contains rivastigmine hydrogen tartrate corresponding to rivastigmine 4.5 mg.
- The other ingredients in the capsules are:
  Capsule contents: hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose (E460), and colloidal anhydrous silica (E551).
  Capsule shell: gelatin (E441), yellow iron oxide (E172), red iron oxide (E172) and titanium dioxide (E171). The printing ink contains shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Rivastigmine DEMO 6.0 mg capsules, hard contains

- The active substance is rivastigmine. Each capsule contains rivastigmine hydrogen tartrate corresponding to rivastigmine 6.0 mg.
- The other ingredients in the capsules are:
  Capsule contents: hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose (E460), and colloidal anhydrous silica (E551).

Capsule shell: gelatin (E441), yellow iron oxide (E172), red iron oxide (E172) and titanium dioxide (E171). The printing ink contains shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide, potassium hydroxide and black iron oxide (E172).

What Rivastigmine DEMO looks like and contents of the pack
Capsules, hard
Rivastigmine DEMO 1.5 mg capsules, hard are hard gelatin capsules, with a yellow coloured body and a yellow coloured cap. The cap is imprinted radially with "R9VS" above "1.5" in black ink.
Rivastigmine DEMO 3.0 mg capsules, hard are hard gelatin capsules, with a yellow coloured body and a orange coloured cap. The cap is imprinted radially with "R9VS" above "3" in black ink.
Rivastigmine DEMO 4.5 mg capsules, hard are hard gelatin capsules, with a red coloured body and a red coloured cap. The cap is imprinted radially with "R9VS" above "4.5" in black ink.
Rivastigmine DEMO 6.0 mg capsules, hard are hard gelatin capsules, with a yellow coloured body and a red coloured cap. The cap is imprinted radially with "R9VS" above "6" in black ink.
They are packed in blisters available in different pack sizes (7, 10, 14, 28, 30, 56, 98, 112 capsules).
Not all pack sizes may be marketed.

Marketing authorisation holder
DEMO S.A. Pharmaceutical Industry
21st Km National Road Athens-Lamia
14568 Krioneri
Griekenland

Manufacturer responsible for batch release
DEMO S.A. Pharmaceutical Industry
21st Km National Road Athens-Lamia
14568 Krioneri
Griekenland

Marketing Authorization Number (s)
Rivastigmine DEMO 1,5 mg, capsules, hard: RVG 103038
Rivastigmine DEMO 3,0 mg, capsules, hard: RVG 103039
Rivastigmine DEMO 4,5 mg, capsules, hard: RVG 103040
Rivastigmine DEMO 6,0 mg, capsules, hard: RVG 103041

Deze bijsluiter is voor de laatste keer goedgekeurd in december 2019