

Package leaflet: information for the patient

Rivastigmine 2 mg/ml oral solution

(Rivastigmine)

(Referred in this leaflet as 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. What Rivastigmine is and what it is used for
2. What you need to know before you take Rivastigmine
3. How to take Rivastigmine
4. Possible side effects
5. How to store Rivastigmine
6. Contents of the pack and other information

1. WHAT RIVASTIGMINE IS AND WHAT IT IS USED FOR

The active substance 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 level of acetylcholine to be increased in the brain, helping to reduce symptoms of Alzheimer's disease and dementia associated with Parkinson's disease.

Rivastigmine 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 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

Do not take Rivastigmine

- if you are allergic to rivastigmine (the active substance in Rivastigmine) or any of the other ingredients of this medicine (listed in section 6),

If this applies to you, tell your doctor and do not take Rivastigmine.

Warnings and precautions

Talk to your doctor before taking Rivastigmine:

- if you have, or have ever had, irregular or slow heartbeat.
- if you have had a heart attack or have heart failure.
- if you have ever had low blood levels of potassium or magnesium.
- if you have severe dementia or other types of memory impairment.
- 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 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 taking this medicine.

If you have not taken Rivastigmine for 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 in the paediatric population in the treatment of Alzheimer's disease.

Other medicines and Rivastigmine

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

Rivastigmine should not be given at the same time as other medicines with similar effects to Rivastigmine. Rivastigmine may

interfere with the action of other anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness).

Rivastigmine 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 Rivastigmine, tell your doctor before you are given any anaesthetics, because Rivastigmine may exaggerate the effects of some muscle relaxants used during anaesthesia.

Tell your doctor or pharmacist if you are taking any antipsychotic medicines e.g. chlorpromazine, amisulpride, pimozide, citalopram, pentamidine. Taking these with rivastigmine may cause your heart rate to slow.

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

You should not breast-feed during treatment with Rivastigmine.

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.

Rivastigmine contains sodium benzoate

Mildly irritant to the skin, eyes and mucous membranes.

3. HOW TO TAKE RIVASTIGMINE

Always take Rivastigmine as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to start treatment

Your doctor will tell you what dose of Rivastigmine to take.

- Treatment usually starts with a low dose
- Your doctor will slowly increase your dose depending on how you respond to the 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 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.

How to use this medicine

1. Prepare the bottle and syringe

- Remove the syringe from the holder.

- Push down and turn the child resistant cap to open the bottle.

2. Attaching the syringe to the bottle

- Push the nozzle of the syringe into the hole in the white stopper.

3. Filling the syringe

- Pull the plunger upwards until it reaches the right mark for the dose that your doctor has prescribed.

4. Removing bubbles

- Push down and pull up the plunger a few times to get rid of any large bubbles.

- A few tiny bubbles are not important and will not affect your dose in any way.

- Check the dose is correct.

- Then remove the syringe from the bottle. The stopper will remain in the neck of the bottle.

5. Taking your medicine

• Either swallow your medicine direct from the syringe or first mix with water in a small glass, stir and drink all of the mixture.

6. After using the syringe

- Wipe the outside of the syringe with a clean tissue.
- Then, put the syringe back into its protective holder.
- Put the child resistant cap back on the bottle to close it.

If you take more Rivastigmine than you should

If you accidentally take more Rivastigmine than you should, inform your doctor. You may require medical attention. Some people who have taken too much of this medicine have experienced digestive problems such as stomach pain, feeling sick (nausea), being sick (vomiting) and diarrhoea, flushing of the skin, change in the size of the pupils in the eyes, high, or low blood pressure, slow heartbeat, difficulty breathing, increase of mucus from the lungs, excessive sweating, increased saliva in the mouth, tears, urinary or bowel incontinence, dizziness, shaking, fainting, headache, drowsiness, confusion, hallucinations and feeling unwell. In addition, muscle weakness, muscle twitching, fits or breathing stopped may develop with possible fatal outcome.

If you forget to take Rivastigmine

If you notice that you have forgotten to take your dose of Rivastigmine, wait until the next dose at the usual time. Do not take two doses to make up for the missed 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 Rivastigmine can cause side effects although not all patients will get them.

You may have side effects more often when you start taking the medicine or when your dose is increased. Usually the side effects will slowly go away as your body becomes 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)

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

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

Rarely (may affect up to 1 in 1,000 people)

- Chest pain
- Rash
- 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 eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)
- Aggression, feeling restless
- Uneven heartbeat

- Itching

Patients with dementia and Parkinson's disease

These patients have some side effects more often.

They also have some additional effects:

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

- Trembling
 - Accidental falling
- Common** (may affect up to 1 in 10 people)
- Decreased appetite
 - Anxiety
 - Feeling restless
 - Slow 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
 - High blood pressure
 - Hallucination, visual
 - Depression

Uncommon (may affect up to 1 in 100 people)

- Uneven heartbeat and poor control of movements

- Low blood pressure

Not known

- Skin Rash

Other side effects seen with rivastigmine transdermal patches and which may occur with the oral solution:

Common (may affect up to 1 in 10 people)

- Fever
- Severe confusion
- Decreased appetite
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE RIVASTIGMINE

Keep this medicine out of the sight and reach of children.

Do not use Rivastigmine after the expiry date which is printed on the carton and the bottle label. The expiry date refers to the last day of the month.

Store Rivastigmine below 25°C. Do not refrigerate or freeze.

Keep the container in outer carton in order to protect from light. Store in an upright position.

Use Rivastigmine within 1 month of opening the bottle. A space on the bottle label is provided so that the date of first opening can be recorded.

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 contains

- The active substance is rivastigmine hydrogen tartrate. Each ml contains rivastigmine hydrogen tartrate corresponding to 2 mg rivastigmine base.
- The other ingredients are sodium benzoate (E211), citric acid monohydrate, sodium citrate dihydrate, quinoline yellow (E104) and purified water.

What Rivastigmine looks like and contents of the pack

Rivastigmine oral solution is a clear yellow solution. It is supplied as 120 ml in an amber glass bottle with a child resistant cap with an adaptor for the oral dosing syringe (included in the pack).

Marketing Authorisation holder: Beacon Pharmaceuticals Limited, DCC Vital, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England.

Manufacturer: Kleva Pharmaceuticals SA, 189 Parnithos Avenue, 13675 Acharnai, Greece.

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