

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rivastigmine 1.5 mg, 3 mg, 4.5 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.

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1. What Rivastigmine is and what it is used for

The active substance of Rivastigmine Hard Capsules 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 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 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

Do NOT take Rivastigmine

[1.5mg:]

- if you are **allergic** to rivastigmine, other carbamate derivatives, sunset yellow FCF (E110), tartrazine (E102) or any of the other ingredients of this medicine (listed in section 6)

[3mg:]

if you are allergic to rivastigmine, other carbamate derivatives, ponceau 4R red (E124), sunset yellow FCF (E110), tartrazine (E102) or any of the other ingredients of this medicine (listed in section 6)[4.5mg:]

- if you are allergic to rivastigmine, other carbamate derivatives or any of the other ingredients of this medicine (listed in section 6)
- if you have had a previous skin reaction suggestive of **allergic contact dermatitis** with rivastigmine patches.

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 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**
- 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 Rivastigmine 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 in the paediatric population in the treatment of Alzheimer's disease.

Other medicines and Rivastigmine

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

Rivastigmine should not be given at the same time as other medicines with similar effects to Rivastigmine. Rivastigmine might interfere with 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, you should inform the doctor before you are given any **anaesthetics**, because Rivastigmine may exaggerate the effects of some muscle relaxants during anaesthesia.

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 and breast-feeding

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 1.5 mg contains Sunset yellow FCF (E110) and tartrazine (E102)

which may cause allergic reactions.

Rivastigmine 3 mg contains Ponceau 4R red (E124),
sunset yellow FCF (E110) and tartrazine (E102)

which may cause allergic reactions.

3. How to take Rivastigmine

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 Rivastigmine 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 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 heart beat and fainting may also occur.

If you forget to take Rivastigmine

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 product, 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 taking 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):

- nightmares
- anxiety
- sweating
- headache
- heartburn
- weight loss
- stomach pain
- feeling agitated
- feeling tired or weak
- generally feeling unwell
- trembling or feeling confused
- decreased appetite

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

- depression
- difficulty in sleeping
- fainting or accidentally falling
- changes in how 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 heart beat 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 1,00 people):

- uneven heart beat and poor control of movements

Other side effects seen with Rivastigmine 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 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 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 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

Rivastigmine contains

The active substance is rivastigmine.

Rivastigmine 1.5 mg, 3 mg, 4.5 mg Capsules contain 1.5 mg, 3 mg, 4.5 mg rivastigmine as rivastigmine hydrogen tartrate, respectively.

The other ingredients are:

Capsule contents

Hypromellose 5mPa·s, Microcrystalline Cellulose, Silica, colloidal anhydrous, Magnesium Stearate.

Capsule shell

1.5 mg:

Titanium Dioxide (E171), Gelatin, Water, purified, Sodium Laurilsulfate, Tartrazine (E102), Sunset Yellow FCF (E110). Ink used for imprinting: Shellac, Sodium hydroxide, Titanium dioxide (E171), Povidone K16 and Allura red (E129).

3 mg:

Titanium Dioxide (E171), Gelatin, Water, purified, Sodium Laurilsulfate, Brilliant Blue (E133), Ponceau 4R red (E124), Sunset Yellow FCF (E110), Tartrazine (E102). Ink used for imprinting: Shellac, Sodium hydroxide, Titanium dioxide (E171), Povidone K16 and Allura red (E129).

4.5 mg:

Titanium Dioxide (E171), Gelatin, Water, purified, Sodium Laurilsulfate, Iron oxide red (E172), Iron oxide yellow (E172). Ink used for imprinting: Shellac, Sodium hydroxide, Titanium dioxide (E171) and Povidone K16.

What Rivastigmine looks like and contents of the pack

Capsule, hard

1.5 mg: White to off-white powder in a hard gelatin capsule (size 2) with yellow opaque cap and yellow opaque body, imprinted "RV, 1.5" on body with red ink.

3 mg: White to off-white powder in a hard gelatin capsule (size 2) with light orange opaque cap and light orange opaque body, imprinted "RV, 3" on body with red ink.

4.5 mg: White to off-white powder in a hard gelatin capsule (size 2) with red opaque cap and red opaque body, imprinted "RV, 4.5" on body with white ink.

Rivastigmine Capsules are available in blister packs of 14, 28, 30, 56 or 112 capsules, hard. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Road, Beverley, HU17 0LD.

This medicinal product is also authorised in the Member States of the EEA under the following names:

Germany: Rivastigmin beta 1.5 mg, 3 mg, 4.5 mg Hartkapseln

Romania: Rivastigmina Dr. Reddy's 1.5 mg, 3 mg, 4.5 mg capsule

This leaflet was last revised in 12/2019.