

Package leaflet: Information for the patient

Rivastigmine 1.5 mg capsules

Rivastigmine 3 mg capsules

Rivastigmine 4.5 mg capsules

Rivastigmine 6 mg 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 or pharmacist.
- 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 of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is 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 of this medicine 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.

This medicine 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.

This medicine can also be used for the treatment of mild to moderately severe dementia in adult patients with Parkinson's disease.

2. What you need to know before you take Rivastigmine

Before taking this medicine it is important that you read the following section and discuss any questions you might have with your doctor.

Do not take Rivastigmine

- if you are allergic to rivastigmine, or to any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines known as 'carbamate derivatives' such as neostigmine used in the treatment of myasthenia gravis (a disease which affects the nerves and muscles) and darunavir used to treat HIV infection.
- if you have previously used rivastigmine as a transdermal patch and have had a skin reaction spreading beyond the patch size, with a more intense local reaction (such as blisters, increasing skin inflammation, swelling) and not improving within 48 hours after removal of the transdermal patch.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Rivastigmine:

- 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 heart failure.
- If you have had a heart attack.
- If you have, or have ever had, low levels of potassium or magnesium in your blood.
- 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 have a low body weight, (below 50 kg).

If any of these apply to you, your doctor may need to monitor you more closely while you are on this medicine.

During treatment

Contact your doctor if you notice any of the following:

- If you suffer from trembling.
- 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.
- You develop skin irritation or skin blistering.
- You experience seeing, hearing and feeling things that are not there or you notice that you are shaking, especially if this happens shortly after your doctor has increased your dose.
- You are constantly sick, especially if you have just started taking a higher dose than normal. - You notice that you are losing weight.

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 this medicine for the treatment of Alzheimer's disease in the paediatric population.

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, to relieve bladder problems (needing to pass water more often or incontinence) e.g. oxybutynin, tolterodine or to prevent travel sickness).

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

Caution should be exercised when rivastigmine is taken together with medicines known as betablockers e.g. atenolol (used to treat high blood pressure, angina and other heart conditions) or timolol (used in eye drops to treat glaucoma). Caution is also required with other medicines which may lower heart rate or rhythm e.g. diltiazem, sotalol, digoxin, pilocarpine. Taking the two medicines together could cause problems such as slowing of the heartbeat (bradycardia) leading to fainting or loss of consciousness.

Caution when rivastigmine is taken together with other medicines that can affect your heart rhythm or the electrical system of your heart (QT prolongation).

If you are taking other medicines known to affect the normal rhythm of the heart e.g. chlorpromazine, levomepromazine, sulpiride, sultopride, amisulpride, tiapride, vernalipride, pimozone, haloperidol, droperidol (used to treat some mental health conditions), cisapride (used to treat stomach and gut problems), citalopram (used to treat depression), diphemanil (used to treat in stomach disorders), erythromycin IV, moxifloxacin, (antibiotics), halofantrine (used to treat malaria), mizolastine (used to treat allergies), methadone (used for pain and to treat heroin addiction) and pentamidine (a medicine used to treat pneumonia), your doctor may want to carry out regular checks on your heart.

Pregnancy and breastfeeding

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 this medicine must be assessed against the possible effects on your unborn child. This medicine 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 (feeling sleepy), 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

Always take this medicine exactly as your doctor or pharmacist 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 this medicine 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 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 this medicine 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. - 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 a decrease in the size of the pupils, flushing, stomach pain, difficulty in breathing and increase in phlegm, increased sweating, loss of control of bowel movements, incontinence, increase in production of saliva, increase in tear production, low blood pressure, feeling sick (nausea), being sick (vomiting), diarrhoea, high blood pressure and hearing, seeing and feeling things that are not there (hallucinations). Slow heartbeat and fainting may also occur. In severe cases, muscular weakness, twitching, fits and stopping breathing which may be fatal have occurred. Additionally there have also been reports of dizziness, shaking, headache, excessive sleepiness, confusion, and a general feeling of discomfort (malaise).

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 stop taking Rivastigmine

Do not stop taking your capsules. It is important that you carry on taking Rivastigmine for as long as your doctor tells you. 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 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.

If any of the following serious side effects occur, **tell your doctor or seek medical advice immediately:**

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

- Fits (seizures)
- Chest pain that may become worse when exercising □ Ulcers in your stomach or intestine

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

- Inflammation of the pancreas, which shows as **serious** upper stomach pain, often with symptoms such as 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

- Irregular heartbeat, which you may notice as an uneven heart beat or skipping a beat □
Bleeding in the gut – shows as blood in stools or when being sick

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)
- 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)

Other possible side effects:

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
- Drowsiness
- 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, which may show up in tests

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

- Rash

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

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

- Aggression, feeling restless
- Uneven heartbeat
- Losing too much fluid (dehydration)
- Itching
- Widespread skin reaction
- 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:

If any of the following serious side effects occur, tell your doctor or seek medical advice immediately:

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

- 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 heart beat

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

- Yellowing of the skin or whites of the eyes, which may indicate liver problems

Other possible side effects

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

- Trembling
- Accidentally falling

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

- Diarrhoea
- Dizziness
- Feeling restless
- Slow heartbeat
- High blood pressure
- Difficulty in sleeping
- Seeing things that are not there (hallucinations)
- Depression
- Too much saliva and dehydration
- Unusually slow movements or movements you cannot control

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

- 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)

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
- Decreased appetite
- Inability to retain adequate urine (urinary incontinence)

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

- High level of activity, restlessness (hyperactivity)

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

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any 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. 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 (EXP) that is stated on the blister/bottle and the carton. 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 contains**

The active substance is rivastigmine.

Each Rivastigmine 1.5 mg capsule contains 1.5 mg of rivastigmine.

Each Rivastigmine 3 mg capsule contains 3 mg of rivastigmine.

Each Rivastigmine 4.5 mg capsule contains 4.5 mg of rivastigmine.

Each Rivastigmine 6 mg capsule contains 6 mg of rivastigmine.

The other ingredients are:

Contents of Capsule: Cellulose, microcrystalline, Hypromellose, Magnesium stearate, Silica, colloidal anhydrous

Capsule Shell: Yellow iron oxide (E172), Red iron oxide (E172) (3 mg, 4.5 mg, and 6 mg only), Titanium dioxide (E171), Gelatin

Printing Ink:

Red Ink (1.5 mg, 3 mg and 4.5 mg): Iron oxide red (E172), Shellac, Propylene glycol (E1520), Ammonia, Potassium hydroxide.

White Ink (6 mg only): Shellac, Titanium dioxide (E171), Propylene glycol (E1520).

What Rivastigmine looks like and contents of the pack

Your medicine comes as a hard capsule containing a white powder.

The 1.5 mg capsule has a yellow body marked “RG 15” in red ink, and a yellow cap marked with “G” in red ink.

The 3 mg capsule has an orange body marked “RG 30” in red ink, and an orange cap marked with “G” in red ink.

The 4.5 mg capsule has a reddish-brown body marked “RG 45” in red ink, and a reddish-brown cap marked with “G” in red ink.

The 6 mg capsule has an orange body marked “RG 60” in white ink, and a reddish-brown cap marked with “G” in white ink, containing a white powder.

Rivastigmine capsules are available in blister and bottle packs of 10, 28, 30, 56, 60, 90, 112, 250 and 500. Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer:

McDermott Laboratories trading as Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft, Mylan utca 1., Komárom, 2900, Hungary

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