

RIVADEM CAPSULES

Rivastigmine Hydrogen Tartrate (1.5mg, 3.0mg, 4.5mg, 6.0mg)

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What RIVADEM is used for

Rivadem Capsules is indicated for the treatment of mild to moderate dementia of the Alzheimer's type (a progressive brain disorder that gradually affects memory, thinking and behaviour).

How RIVADEM works

Rivastigmine belongs to a class of substances called cholinesterase inhibitors.

Rivastigmine improves the function of nerve cells in the brain. It works by preventing the breakdown of a chemical called acetylcholine by blocking the enzymes that break it down. This chemical is needed to help keep the brain working properly.

Rivastigmine helps to slow down the mental decline that happens in people with Alzheimer's disease and it helps to improve the ability to cope with everyday activities.

Before you use RIVADEM

- When you must not use it

Do not take Rivadem if you have:

- Hypersensitivity to rivastigmine, other carbamate derivatives or other ingredients of Rivadem.
- Severe liver impairment.

Pregnancy and lactation

Do not take Rivadem if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Rivadem if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Please tell your doctor if you have:

- Gastrointestinal disorder such as nausea and vomiting
- Stomach or duodenal ulcer, difficulties in passing urine, seizures and low body weight
- A heart rhythm disorder.
- High blood pressure, hallucinations (hear, smell, taste or feel things that do not exist).
- Parkinson's disease.
- History of asthma or breathing problems.
- Tell the doctor if you have, or have ever had heart conditions such as irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have low potassium or magnesium. Your doctor may need to monitor you more closely while you are on this medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Rivastigmine should not be given concomitantly with muscle relaxants.

Caution when RIVADEM is taken together with medicinal product know to prolong the heart's electrical system (QT interval) [including but not limited to quinidine (medicine used to treat irregular heartbeat), amiodarone (medicine used to treat serious/fatal irregular heartbeat), pimozide (medicine works on central nervous system), halofantrine (antimalaria medicine), cisapride (medicine used to treat symptoms of night-time heartburn), citalopram (medicine used to treat depression), mizolastin (antihistamine medicine), medicine used to treat bacterial infection such as moxifloxacin, erythromycin. Your doctor may also monitor your clinical condition as needed.

How to use RIVADEM

- How much to use

The starting dose of Rivadem Capsules is 1.5 mg twice a day. If this dose is well tolerated, after a minimum of two weeks of treatment, the dose may be increased to 3 mg twice a day. Subsequent increases to 4.5 mg twice a day and 6 mg twice a day should be attempted after a minimum of 2 weeks at the previous dose.

If adverse effects (e.g., nausea, vomiting, abdominal pain, loss of appetite) cause intolerance during treatment, the individual should be instructed to discontinue treatment for several doses and then restart at the same or next lower dose level. If treatment is interrupted for longer than several days, treatment should be reinitiated with the lowest daily dose. The maximum dose is 6 mg twice a day (12mg/day).

- When to use it

Rivadem Capsules should be taken with meals in divided doses in the morning and evening.

- How long to use it

Continue taking Rivadem Capsules for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many capsules may cause nausea, vomiting and diarrhea, high blood pressure or hallucinations.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Rivadem Capsules.
- Tell your doctor immediately if you become pregnant while taking this medication.

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- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Rivadem Capsules to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of Driving and using machines

This medicine may affect your ability to drive or use machines. Rivastigmine may cause dizziness and sleepiness, mainly at the start of treatment or when increasing the dose. If you feel dizzy or sleepy, do not drive or operate machines and contact your doctor immediately.

Side effects

Like all medicines, Rivadem Capsules can cause side effects, although not everybody gets them.

Very common and common side effects are:

- Dizziness.
- Nausea.
- Vomiting.
- Diarrhoea.
- Loss of appetite.
- Agitation.
- Confusion.
- Headache.
- Sleepiness.
- Shaking.
- Abdominal pain.
- Indigestion.
- Sweating increased.
- Fatigue.
- Lack of energy.
- Feeling of general discomfort, uneasiness or ill.
- Weight loss.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website <http://nptra.gov.my> (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of RIVADEM

- Storage

- Store below 30°C. Protected from moisture.
- Keep out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- What it looks like

RIVADEM 1.5 MG CAPSULES:

Hard gelatin opaque yellow capsule containing off white to slightly yellow powder.

RIVADEM 3 MG CAPSULES:

Hard gelatin opaque orange capsule containing off white to slightly yellow powder.

RIVADEM 4.5 MG CAPSULES:

Hard gelatin opaque red capsule containing off white to slightly yellow powder.

RIVADEM 6 MG CAPSULES:

Hard gelatin capsule with opaque red cap and opaque orange body, containing off white to slightly yellow powder.

- Ingredients

- Active ingredient:

- Rivastigmine Hydrogen Tartrate.

- Inactive ingredients:

- Cellulose microcrystalline.
- Hypromellose.
- Colloidal silicon dioxide.
- Magnesium stearate.

- MAL number(s):

RIVADEM 1.5 MG CAPSULES:

MAL09042434AZ

RIVADEM 3 MG CAPSULES:

MAL09042435AZ

RIVADEM 4.5 MG CAPSULES:

MAL08120885AZ

RIVADEM 6 MG CAPSULES:

MAL09042436AZ

Manufacturer

Torrent Pharmaceuticals LTD.
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Product Registration Holder

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