
Consumer Medicine Information

RIMANE

1.5mg, 3mg, 4.5mg and 6mg Capsules
Rivastigmine hydrogen tartrate

What is in this leaflet

This leaflet answers some common questions about RIMANE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking it against the benefits they expect it will have for you.

If you have any concerns about taking RIMANE capsules, ask your doctor or pharmacist for more information.

Keep this leaflet with the medicine. You may want to read it again.

What RIMANE is used for

RIMANE is used to help slow the progression of a condition called Alzheimer's disease.

Alzheimer's disease is a condition in which changes in the brain cause problems with memory, thinking and behaviour. These problems gradually become worse with time.

RIMANE works by preventing the breakdown of a chemical in the brain called acetylcholine. This chemical is needed to help keep the brain working properly.

RIMANE 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. It does not cure the condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

RIMANE has been approved for the uses mentioned above. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor.

RIMANE is only available with a doctor's prescription. There is no evidence that RIMANE capsules are addictive.

Before you take RIMANE

When you must not take it

Do not take RIMANE if you have had an allergic reaction to any of the following:

- rivastigmine, the active ingredient in RIMANE capsules
- any of the other ingredients of RIMANE capsules listed at the end of this leaflet.
- other related "carbamate" medicines (if you are unsure about these, ask your doctor or pharmacist)
- Symptoms of an allergic reaction may include wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash or hives on the skin.

Do not take RIMANE if you have a severe liver disorder.

There is no information on the use of this medicine in people with severe liver problems.

Do not take RIMANE after the expiry date printed on the pack.

If you use it after the expiry date has passed, it may not work as well as it should.

Do not take RIMANE if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Do not give RIMANE to children.

It is not known how Rivastigmine will affect children.

If you are not sure whether you should start taking RIMANE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have any of the following conditions:

- diseases of the heart , including high or low blood pressure
- stomach ulcer or history of stomach ulcers
- lung disease such as asthma or obstructive pulmonary disease
- bladder problems or difficulty passing urine
- seizures (fits)
- Problems with your kidney or liver
- gastro-intestinal reactions such as nausea (feeling sick) and vomiting (being sick).

If you have any of the above conditions your doctor may want to take special precautions while you are taking Rivastigmine.

Tell your doctor if:

- you are pregnant or planning to become pregnant
- breast-feeding.

It is not known whether taking RIMANE during pregnancy may affect your baby. Breast-feeding is not recommended while you are taking this medicine. It is not known whether the active ingredient in Rimane passes into the breast milk and could affect your baby.

Ask your doctor about the risks and benefits of taking RIMANE in this case.

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.

Rimane may affect other medicines or other medicines may affect how well Rimane works.

These include:

- cholinergic medicines (e.g. bethanecol, medicines used during surgery)
- anticholinergic medicines (e.g. medicines for stomach cramps, medicines for travel sickness, many medicines used to treat mental illness)

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Rimane.

If you have not told your doctor about any of these things, tell him/her before you take RIMANE.

How to take RIMANE capsules

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual starting dose is 1.5 mg twice a day. After two weeks, if you don't have any problems with the medicine, the dose may be gradually increased up to a maximum of 6 mg twice a day.

If for any reason you stop taking RIMANE for more than several days, tell your doctor before you start taking RIMANE again.

Your doctor will restart you at the lowest dose to help prevent side effects such as nausea and vomiting.

How to take it

Swallow the capsules whole with a full glass of water or other liquid, with your morning and evening meals.

Do not open or crush the capsules.

Take RIMANE at about the same time each day.

Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take the capsules.

How long to take it

Continue taking RIMANE for as long as your doctor tells you to.

This medicine helps to slow the progression of Alzheimer's disease but does not cure it. Your treatment can be continued for as long as it benefits your condition. Your doctor can give you more information.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

Immediately contact a doctor or Poisons Information Centre (telephone 0800 POISON and 0800 764 766), or go to the your nearest Accident and Emergency department or clinic, if you think that you or someone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

The most common signs and symptoms of rivastigmine overdose include severe nausea (feeling sick), vomiting, diarrhoea, hypertension and hallucinations. A slow heartbeat and breathing, excess saliva, sweating, low blood pressure, muscle weakness, fainting and seizures (fits) may also happen.

While you are taking RIMANE

Things you must do

- Follow your doctor's instructions carefully.
 - Seek your doctor's advice before you change or stop taking this medicine.
 - Be sure to keep all of your doctor's appointments so your progress can be checked.
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Make sure you or your caregiver tell your doctor if you experience considerable nausea and vomiting with loss of appetite and weight loss.

If you become pregnant while taking RIMANE, tell your doctor.

If you are going to have surgery, tell your doctor and anaesthetist that you are taking RIMANE.

RIMANE may affect some medicines you receive during surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RIMANE.

Tell any other doctor, dentist or pharmacist who treats you that you are taking RIMANE.

Things you must not do

Do not give this medicine to anyone else, even if his or her condition seems similar to yours.

Do not use RIMANE to treat any other complaints unless your doctor tells you to.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RIMANE, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting
 - diarrhoea
 - loss of appetite
 - stomach pains
 - gastrointestinal ulcers
 - gastrointestinal haemorrhage
 - mild pancreatitis
 - indigestion, burping, wind
 - constipation
 - weight loss
 - dizziness)
 - headache
 - unable to sleep
 - unusual tiredness or weakness, sleepiness, feeling generally unwell
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- trembling or shakiness
 - aches and pains
 - anxiety
 - agitation or aggressive feelings
 - nervousness
 - depression
 - hallucinations (hearing or seeing things that are not there)
 - confusion
 - unusual thinking (e.g. delusions, feeling paranoid)
 - increased sweating
 - runny or blocked nose
 - increase in blood pressure
 - slow heart beat
 - symptoms of flu or chest infections such as shortness of breath, chest congestion, cough or sore throat
 - frequent urge to urinate, pain on urination,
 - loss of bladder control
 - swelling of lower legs and hands due to fluid build up

The above side effects usually happen at the start of treatment when the dose is being increased. They are not usually serious and may gradually disappear as your body gets used to the medicine.

Women are more likely than men to get some side effects (e.g. nausea, vomiting, loss of appetite, weight loss).

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing
- chest pain
- heart attack (crushing chest pain)
- severe dizziness, fainting or fits (seizures)
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- severe vomiting that can lead to a rupture of the oesophagus
- changes in liver function tests may also occur
- stroke (loss of coordination, difficulty in speaking or breathing and signs of brain disorder), severe confusion

The above side effects may be serious. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything else that is making you unwell.

Other side effects not listed above may happen in some people.

Storage conditions

Keep your tablets in the original container until it is time to take them. If you leave the tablets out of the original container they will not keep well.

Keep your tablets in a cool dry place away from light where the temperature stays below 30°C.

Do not store your tablets or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a windowsill.

Heat and dampness can destroy medicines.

As with all medicines, you should store your tablets out of the reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

RIMANE is available in four strengths, in packs of 30 and 100 capsules.

- RIMANE 1.5 mg: yellow hard gelatin capsules, body printed with "R 1.5".
- RIMANE 3.0 mg: orange hard gelatin capsules, body printed with "R 3.0".
- RIMANE 4.5 mg: red hard gelatin capsules, body printed with "R, 4.5".
- RIMANE 6.0 mg: hard gelatin capsules, red cap and orange body, body printed with "R 6.0".

Ingredients

RIMANE capsules contain 1.5, 3.0, 4.5 or 6.0 mg of the active ingredient, rivastigmine (as the hydrogen tartrate salt).

They also contain:

- magnesium stearate
 - hypromellose
 - colloidal anhydrous silica
 - microcrystalline cellulose
 - gelatin
 - sodium lauryl sulphate
 - iron oxide red (E172)
 - iron oxide yellow (E172)
 - titanium dioxide (E171)
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Sponsor

RIMANE capsules are supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
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