

Rivastigmelon Patch

Rivastigmine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rivastigmelon Patch.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.ebs.tga.gov.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Rivastigmelon Patch is used for

Rivastigmelon Patch contains rivastigmine as the active substance. Rivastigmine belongs to a class of substances called cholinesterase inhibitors and is used to treat a condition called Alzheimer's disease.

In patients with Alzheimer's dementia, 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). This causes changes in the brain and problems with memory, thinking and behaviour. These problems gradually become worse with time.

Rivastigmelon Patch works by preventing the breakdown of acetylcholine. This chemical is needed to help keep the brain working properly.

Rivastigmine helps to reduce the symptoms of Alzheimer's disease, to slow down the mental decline that happens in people with this condition, and helps to improve the patient's 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.

Your doctor may have prescribed it for another reason.

Rivastigmelon Patch is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend this medicine for children.

Before you apply Rivastigmelon Patch

When you must not use it

Do not apply Rivastigmelon Patch if you have had an allergic reaction to any of the following:

- rivastigmine, the active ingredient in Rivastigmelon Patch
- any of the other ingredients of Rivastigmelon Patch 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 apply Rivastigmelon Patch 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 apply Rivastigmelon Patch if you have had a skin reaction which has spread beyond the patch size, if there was a more intense local reaction (such as blisters, increasing skin inflammation, swelling) and if it did not improve within 48 hours after removal of the transdermal patch.

Do not apply Rivastigmelon Patch after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

Do not use Rivastigmelon Patch in children.

It is not known how Rivastigmelon Patch will affect children.

If you are not sure whether you should start using Rivastigmelon Patch, talk to your doctor or pharmacist.

Before you start to use it

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

- a problem with your heart

- a history of stomach ulcer
- problems with your lungs such as asthma or obstructive pulmonary disease
- emphysema
- difficulty passing urine (water)
- seizures (fits)
- problems with your kidneys or liver
- problems with your stomach such as nausea (feeling sick) and vomiting (being sick)
- if you have a low body weight (less than 50 kg)

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

Tell your doctor if you are pregnant or breast-feeding.

It is not known whether using Rivastigmelon Patch during pregnancy or while breast-feeding could affect your baby.

Breast-feeding is not recommended while you are using this medicine. It is not known whether the active ingredient passes into breast milk and could affect your baby.

Tell your doctor if you smoke.

Nicotine can affect the amount of Rivastigmelon Patch that is in your body. A sudden change in your usual smoking habit can also change the effects of Rivastigmelon Patch.

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.

Some medicines and Rivastigmelon Patch may interfere with each other. These include:

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

- metoclopramide (a medicine used to relieve or prevent nausea and vomiting). There may be additive effects such as stiff limbs and trembling hands.
- beta-blockers (medicines used to treat hypertension, angina and other heart conditions). There may be additive effects such as a slow heartbeat that may result in fainting or loss of consciousness.
- non-steroidal anti-inflammatory drugs (NSAIDs), which are medicines used to treat arthritis and other painful conditions such as muscle strains, back pain, menstrual cramps and migraine

You may need to take different amounts of your medicines or to take different medicines while you are using Rivastigmelon Patch. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start using this medicine.

How to use Rivastigmelon Patch

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 to apply Rivastigmelon Patch

Every 24 hours, gently remove any existing patch before putting on a new one. See "How to remove Rivastigmelon Patch".

Having multiple patches on your body could expose you to an excessive amount of this medicine which could be potentially dangerous.

Apply your new patch to a different area of skin.

Before you apply Rivastigmelon Patch, make sure that your skin is:

- clean, dry and hairless
- free of any powder, oil, moisturiser, or lotion (that could keep the patch from sticking to your skin properly)
- free of cuts, rashes and/or irritations.

Apply ONE patch only per day to ONLY ONE of the following locations on your body:

- upper arm, left or right side, or
- chest, left or right side, or
- upper back, left or right side, or
- lower back, left or right side.

To apply the patch:

1. Open the sealed pouch by cutting along the dotted line ensuring you do not cut the patch itself.
2. Remove the Rivastigmelon patch from the pouch.
3. Do not apply the Rivastigmelon patch if it looks damaged in any way. Never cut or divide the patch.
4. Each patch has a protective translucent liner that can be peeled off in two pieces. Remove one side being careful not to touch the adhesive side of the patch.
5. Apply the patch to the skin and peel off the second side of the liner. Press with the palm of the hand for about 30 seconds. Make sure all the transdermal patch is in contact with the skin and stuck tightly.
6. Wash hands after applying or removing the transdermal patch.

Always write the date and time on the pack to help you remember when the next patch is due.

The patch can be used in everyday situations, including bathing and during hot weather.

When changing your patch, you must remove the previous day's patch before you apply your new patch to a different area of skin (for example on the right side of your body one day, then on the left side the next day). Do

not apply a new patch to that same area for at least one week.

How to remove Rivastigmelon Patch

Gently pull at one edge of the Rivastigmelon Patch to remove it completely from the skin.

If any adhesive residue is left on your skin, gently soak the area with warm water and mild soap, or use baby oil to remove it. Do not use alcohol or other dissolving liquids (nail polish remover or other solvents).

Wash your hands with soap and water after removing the patch.

In case of contact with eyes or if the eyes become red after handling the patch, rinse them immediately with plenty of water and seek medical advice if symptoms do not resolve.

How much to use

Your doctor will tell you which Rivastigmelon Patch is more suitable for you. Treatment usually starts with one Rivastigmelon Patch 5 daily.

After about four weeks of treatment the usual daily dose is Rivastigmelon Patch 10. If well tolerated, your doctor may increase the dose to Rivastigmine Patch 15*.

During the course of the treatment your doctor may adjust the dose to suit your individual needs.

Do not wear more than one Rivastigmelon Patch at a time.

If for any reason you stop using Rivastigmelon Patch for more than three days, tell your doctor before you start taking Rivastigmelon Patch again.

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

How long to use it

Apply a new patch every day.

Rivastigmelon Patch should be replaced with a new one after 24 hours.

Apply the new patch at about the same time each day.

Change your patch at the same time each day to obtain the best effect from your medicine. It will also help you remember when to take it.

Continue using Rivastigmelon Patch 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.

Do not stop using Rivastigmelon Patch or change your dose without talking with your doctor.

Switching from Rivastigmine Capsules# to Rivastigmelon Patch

Your doctor will have advised you on switching from Rivastigmine Capsules.

NEVER take Rivastigmine Capsules when using Rivastigmelon Patch.

If you forget to use it

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

Otherwise, apply a new patch as soon as you remember, and then go back to your usual schedule.

Do not apply two Rivastigmelon Patches to make up for the one you missed.

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

Tell your doctor if you have not applied your Rivastigmelon Patch for several days. Do not apply the next patch before you have talked to your doctor.

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

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

If your Rivastigmelon Patch falls off

If your Rivastigmelon Patch falls off, apply a new patch for the rest of the day. Replace this patch the next day at the same time as usual.

Do not re-apply the used patch.

Applying a new patch ensures that your body keeps getting the medicine it needs.

If you use too much (overdose)

If you think that you or anyone else may have accidentally applied more than one Rivastigmelon Patch at a time or swallowed a patch, immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

Because of the way this medicine is used, an intentional overdose is unlikely.

Applying more than one patch or swallowing a patch may cause:

- nausea (feeling sick)
- vomiting
- diarrhoea
- high or low blood pressure
- fainting
- salivation
- sweating
- increasing muscle weakness
- hallucinations (hearing or seeing things that are not there)
- unusually slow heart beat
- breathing difficulties
- convulsions

While you are using Rivastigmelon Patch

Things you must do

Be sure to keep all of your doctor's appointments so your progress can be checked.

You and your caregiver can help to produce the maximum benefit from your treatment by keeping in close contact with your doctor.

Tell your doctor if you smoke.

Nicotine can affect the amount of rivastigmine that is in your body. A sudden change in your usual smoking habit can also change the effects of the rivastigmine patch.

Make sure you or your caregiver tells your doctor if you experience considerable nausea, vomiting or diarrhoea with loss of appetite and weight loss.

You may become dehydrated (losing too much fluid) if vomiting or diarrhoea are prolonged.

Talk to your doctor right away if you have skin inflammation, blisters or swelling of the skin that are increasing and spreading.

If you become pregnant while taking Rivastigmelon Patch, tell your doctor.

There is not enough information to recommend the use of this medicine during pregnancy. Your doctor can discuss with you the risks and benefits involved.

If you are going to have surgery, tell your doctor and anaesthetist that you are using Rivastigmelon Patch.

Rivastigmelon Patch 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 using Rivastigmelon Patch.

Tell any other doctor, dentist or pharmacist who treats you that you are using Rivastigmelon Patch.

Things you must not do

Avoid placing the patch where it might be rubbed off by tight clothing.

Do not give this medicine to anyone else even if their condition seems similar to yours.

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

Do not expose the patch to any external heat sources (excessive sunlight, saunas, and solariums) for long periods of time.

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely.

Rivastigmelon Patch may cause dizziness and somnolence, mainly at the start of treatment or when increasing the dose. Therefore, you should wait to know what effects the drug may cause before engaging in such activities. If you feel dizzy or drowsy, do not drive, use machines or perform any other tasks that require your attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Rivastigmelon Patch, 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 these lists 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
- dehydration (losing too much fluid)
- loss of appetite

- anorexia
- indigestion, abdominal pain or discomfort
- weight loss
- dizziness or a spinning feeling
- headache
- unusual fatigue/tiredness, weakness or sleepiness, feeling generally unwell
- inability to adequately retain urine (urinary incontinence)
- redness, itching, irritation or swelling at the application site
- increased sweating
- difficulty sleeping
- confusion
- mood changes such as feeling aggression, anxious, nervousness, depressed (sad mood)
- unusually high level of activity (hyperactivity)
- hallucinations (hearing or seeing things that are not there)
- loss of control of your bladder or bowels (incontinence).

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
- stroke (loss of coordination, difficulty in speaking and signs of brain disorder)
- unusually fast, slow or irregular heart beat
- raised blood pressure
- unusual thinking (e.g. feeling a fixed, irrational idea not shared

- by others, or feeling strong suspiciousness)
- severe dizziness, fainting or fits (seizures)
- severe confusion
- vomiting blood or material that looks like coffee grounds (gastric ulcer)
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (gastrointestinal haemorrhage)
- severe pain in the abdomen, often with nausea and vomiting (inflammation of the pancreas)
- signs of a urinary tract infection such as frequent urge to urinate or pain on urination
- fits or convulsions
- signs of a liver disorder (yellow skin, yellowing of the whites of eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)
- skin inflammation, blisters or swelling of the skin that are increasing and spreading
- stiff limbs, trembling hands (extrapyramidal symptoms)

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

Some people may have other side effects not yet known or mentioned in this leaflet. Some of the side effects can only be found when your doctor does tests from time to time to check your progress.

After using Rivastigmelon Patch

Storage

- Keep your medicine in the original container (sachet) until it is time to use it.
- Store it in a cool, dry place at room temperature (below 25°C).
- Do not store Rivastigmelon Patch or any other medicine in the bathroom or near a sink

- Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines. Rivastigmelon Patch will keep well if it is kept cool and dry.

Keep the medicine where children cannot reach it.

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

Disposal

After the patch has been removed, fold the patch in half with the adhesive sides on the inside and press them together. Place the folded used patch in its original sachet. Discard safely out of reach and sight of children. Wash your hands with soap and water after removing the patch.

If your doctor tells you to stop using Rivastigmelon Patch or if they have passed their expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Rivastigmelon Patch is available in two strengths, in packs of 30 sachets.

- Patch 5: the outside of the backing layer is translucent white and labelled with "Rivastigmine" and "4.6 mg/24 h"
- Patch 10: the outside of the backing layer is translucent white and labelled with "Rivastigmine" and "9.5 mg/24 h"
- Patch 15: the outside of the backing layer is translucent white and labelled with "Rivastigmine" and "13.3 mg/24 h"

Ingredients

Each Rivastigmelon Patch 5, Patch 10 or Patch 15 contains respectively 9 mg, 18 mg or 27 mg of the active ingredient (rivastigmine). They also contain:

- Acrylates copolymer
- Adhesive matrix (Durotak 87-235A and Bio PSA 7-4302)

Supplier

Rivastigmelon Patches are supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian Registration Numbers:

Rivastigmelon Patch 5: AUST R 233745

Rivastigmelon Patch 10: AUST R 233735

Rivastigmelon Patch 15: AUST R 273560

This leaflet was prepared in October 2017.

* Rivastigmine Patch 15 is available in other brands.

#Rivastigmine capsules are available in other brands

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