

Consumer Medicine Information

Rivastigmine Patch BNM 5 and 10

Rivastigmine

Transdermal Patch 5 (4.6 mg/24 h) and 10 (9.5 mg/24 h)

What is in this leaflet

Please read this leaflet carefully before you start using Rivastigmine Patch BNM.

This leaflet answers some common questions about Rivastigmine Patch BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet 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 Rivastigmine Patch BNM against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What Rivastigmine Patch BNM is used for

Rivastigmine Patch BNM contains rivastigmine as the active ingredient. Rivastigmine belongs to a class of substances called cholinesterase inhibitors and is used to treat 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.

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).

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

Rivastigmine Patch BNM helps to reduce the symptoms of Alzheimer's disease and to slow down the mental decline that happens in people with this condition. It helps to improve the patient's ability to cope with everyday activities. It does not cure the condition.



Your doctor may have prescribed this medicine for another reason.

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

Rivastigmine Patch BNM is only available with a doctor's prescription.

Rivastigmine Patch BNM is not addictive.

Before you use Rivastigmine Patch BNM

Rivastigmine Patch BNM is not suitable for everyone.

When you must not use it

Do not use Rivastigmine Patch BNM if you are allergic to any medicine containing Rivastigmine or any of the ingredients listed at the end of this leaflet.

Do not use Rivastigmine Patch BNM if you have had an allergic reaction to any 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 Rivastigmine Patch BNM 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 use it after the expiry date ('Exp' (as per carton)) printed on the pack.
If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.
In that case, return it to your pharmacist.

Do not use Rivastigmine Patch BNM in children.
It is not known how Rivastigmine Patch BNM will affect children.

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

Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.



Tell your doctor if you have or have had any medical conditions, especially the following:

- a problem with your heart
- a history of stomach ulcer
- problems with your lungs such as asthma or obstructive pulmonary disease
- difficulty passing urine (water)
- seizures (fits)
- problems with your kidneys or liver
- if you experience gastro-intestinal reactions 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 using Rivastigmine Patch BNM.

Tell your doctor if you are pregnant or intend to become pregnant. Ask your doctor about the risks and benefits of using Rivastigmine Patch BNM in this case.

It is not known whether using Rivastigmine Patch BNM during pregnancy may affect your baby.

Do not breast-feed if you are taking this medicine.

It is not known whether the active ingredient in Rivastigmine Patch BNM passes into the breast milk and could affect your baby.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Rivastigmine Patch BNM.

Taking other medicines

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

Tell any healthcare professional who is prescribing a new medicine for you that you are using Rivastigmine Patch BNM.

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

- metoclopramide (a medicine used to alleviate or prevent nausea and vomiting)
- 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)
- medicines called beta blockers, used to treat hypertension, angina, and other heart conditions (e.g. atenolol).

You may need to take different amounts of your medicines or to take different medicines while you are using Rivastigmine Patch BNM.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Rivastigmine Patch BNM.



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

How to use Rivastigmine Patch BNM

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

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

How to apply Rivastigmine Patch BNM

Remove any existing Rivastigmine Patch BNM before putting on a new one. See "How to remove Rivastigmine Patch BNM".

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.

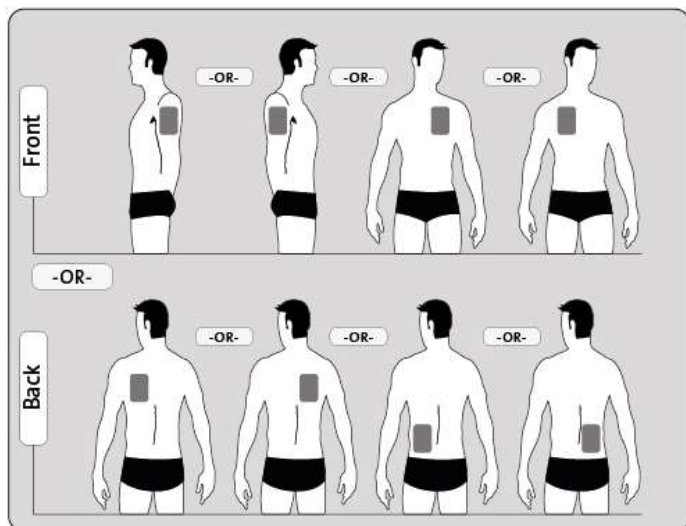
Before you apply Rivastigmine Patch BNM, make sure that your skin is:

- 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.





When changing the patch, you must remove the previous day's patch before you apply the new one to a different location of skin each time (for example on the right side of your body one day, then on the left side the next day, and on your upper body one day, then on your lower body the next day). Do not apply a new patch to that same skin area twice within 14 days.

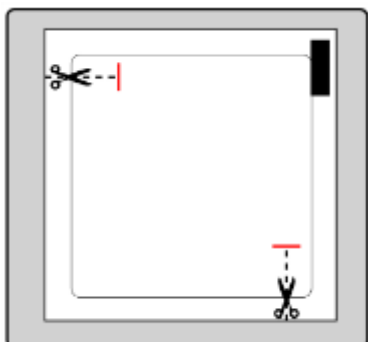
How to apply your patch

Rivastigmine Patch BNM are thin, tan coloured, plastic patches that stick to the skin. Each patch is sealed in a sachet that protects it until you are ready to put it on. Do not open the sachet or remove a patch until just before you apply it.



Carefully remove the existing patch before putting on a new one.

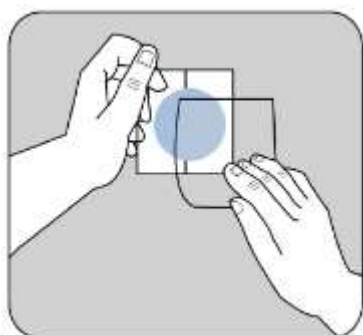
For patients starting treatment for the first time and for patients restarting rivastigmine after treatment interruption, please begin with the second picture.



Each patch is sealed in its own protective sachet. You should only open the sachet when you are ready to apply the patch.

Cut the sachet at both scissors marks, but not further than the indicated line. Tear the sachet to open. Do not cut the entire length of the sachet in order to avoid damaging of the patch.

Remove the patch from the sachet. Remove the cover sheet from the top, skin-coloured side of the patch and discard it.



A protective liner covers the sticky side of the patch.

Peel off one side of the protective liner and do not touch the sticky part of the patch with the fingers.



Put the sticky side of the patch on the upper or lower back, upper arm or chest and then peel off the second side of the protective liner.



Then press the patch firmly in place for at least 30 seconds using the palm of the hand to make sure that the edges stick well.



IMPORTANT:

- **Take off the previous patch before putting ONE new patch on.**
- **Only one patch per day.**
- **Do not cut the patch into pieces.**
- **Press the patch firmly in place for at least 30 seconds using the palm of the hand.**

If it helps you, you may write, for example, the day of the week, on the patch with a thin ball point pen.

The patch should be worn continuously until it is time to replace it with a new one. You may wish to experiment with different locations when applying a new patch, to find ones that are most comfortable for you and where clothing will not rub on the patch.

How to remove Rivastigmine Patch BNM

Gently pull at one edge of the 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

The usual starting dose is Rivastigmine Patch BNM 5 once a day. After a minimum of four weeks, if you don't have any problems with the medicine, the dose may be increased to Rivastigmine Patch BNM 10 once a day. If well tolerated, your doctor may increase the daily dose to to 13.3 mg/24 h. Not all dosing regimens are covered by the strengths of this product.

Do not wear more than one Rivastigmine Patch BNM at a time.

If for any reason you stop using the patch for more than three days, tell your doctor before you start using Rivastigmine Patch BNM. Your doctor will restart you using Rivastigmine Patch BNM 5 to help prevent side effects such as nausea and vomiting.

How to use it

Apply the Rivastigmine Patch BNM at about the same time each day.

Applying your patch at the same time each day will have the best effect. It will also help you remember when to apply the patch.

How long to use it

Apply a new patch every day.

Rivastigmine Patch BNM 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 use it.

Continue using Rivastigmine Patch BNM 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 are unsure whether you should stop using Rivastigmine Patch BNM, talk to your doctor or pharmacist.

If you forget to take it

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

Do not try to make up for missed doses by applying more than one patch at a time.
This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, apply it as soon as you remember, and then go back to using it as you would normally.

Tell your doctor if you have not applied your Rivastigmine Patch BNM for more than three 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use or replace your patches, ask your pharmacist for hints.

If your Rivastigmine Patch BNM falls off

If your Rivastigmine Patch BNM 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.



While you are using Rivastigmine Patch BNM

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Rivastigmine Patch BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that 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.

Make sure you or your caregiver tell your doctor if you experience considerable nausea, vomiting and 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 using this medicine, tell your doctor immediately.

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

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

Do not stop using Rivastigmine Patch BNM or change the dosage without checking with your doctor.

Things to be careful of

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

Rivastigmine Patch BNM 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.



In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have applied accidentally more than one Rivastigmine Patch BNM at a time or swallowed a patch.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Because of the way Rivastigmine Patch BNM is used, an intentional overdose is unlikely. Applying more than one patch or swallowing a patch may cause

- nausea (feeling sick)
- vomiting
- diarrhoea
- high blood pressure
- hallucinations (hearing or seeing things that are not there)
- fainting
- unusually slow heart beat

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Rivastigmine Patch BNM.

Like all medicines, Rivastigmine Patch BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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

- nausea or feeling sick
- vomiting
- passing frequent or watery bowel movements
- loss of appetite
- weight loss
- dizziness or spinning sensation
- headache
- difficulty in sleeping
- nightmares
- abdominal pain
- unusual weakness
- feeling restless or unusually active



- fatigue, tiredness
- skin redness, itching, irritation, swelling (application site reactions)
- skin inflammation with rash
- inability to retain urine adequately (loss of bladder control)
- infection involving the parts of the body producing urine (kidneys, bladder, or the tubes that connect the kidneys to the bladder or the bladder to the outside of the body)
- fall
- muscle stiffness.

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:

- mood changes such as feeling anxious, nervous, agitated, very sad or aggressive
- unusual thinking, severe suspiciousness, or having fixed, irrational ideas not shared by others
- feeling, hearing or seeing things that are not there
- severe confusion
- unusual tiredness or weakness, sleepiness, feeling generally unwell
- increased sweating, losing too much fluid, dehydration
- 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
- irregular, slow or fast heart beat (problems with heart rhythm)
- chest pain
- severe dizziness, fainting or fits (seizures)
- vomiting blood or material that looks like coffee grounds (gastrointestinal haemorrhage)
- blood in stools (bowel motions), bleeding from the back passage, black sticky stools or bloody diarrhoea
- stiff limbs, trembling hands, uncontrollable movements (extrapyramidal signs)
- loss of coordination, difficulty in speaking, or breathing, and signs of brain disorder (stroke)
- severe upper stomach pain, often with nausea and vomiting (inflammation of the pancreas)
- yellow skin, yellowing of the whites of eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite (liver disorders)
- skin inflammation, blisters or swelling of the skin that are increasing and spreading.

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



Some side effects can only be found when your doctor does tests from time to time (e.g. changes in liver function, gastrointestinal ulcers, raised blood pressure).

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

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Rivastigmine Patch BNM

Storage

Keep your patches in the original pack (sachet) until it is time to use them.

If you take the patches out of the pack they may not keep well.

Keep Rivastigmine Patch BNM in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other 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.

Do not keep Rivastigmine Patch BNM past its expiry date.

Disposal

After the patch has been removed, fold it in half with the adhesive sides on the inside and press them together. Return the used patch to its original sachet and discard safely out of the reach and sight of children.

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Rivastigmine Patch BNM is available in two strengths in sachet packs of 30 patches.



- Rivastigmine Patch BNM 5: The patches are of circular shape, printed in orange with "RIV-TDS 4.6 mg/24 h".
- Rivastigmine Patch BNM 10: The patches are of circular shape, printed in orange with "RIV-TDS 9.5 mg/24 h".

Ingredients

Active ingredient:

- Rivastigmine

Inactive ingredients:

Backing layer:

- polyethylene/thermoplastic resin/aluminium coated polyester film

Active layer:

- poly [(2-ethylhexyl)acrylate, vinylacetate]

Adhesive layer:

- medium molecular weight polyisobutene
- high molecular weight polyisobutene
- silica, colloidal anhydrous
- paraffin, light liquid

Release liner:

- polyester film, fluoropolymer-coated

Orange printing ink

Sponsor details

BNM Group
39 Anzac Road
Browns Bay
Auckland 0753

Ph: 0800 565 633

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