

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Exelon 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.novartis.com.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, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Exelon Patch is used for

Exelon 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.

Exelon Patch works by preventing the breakdown of a chemical in the brain called 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.

Exelon 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 Exelon Patch

When you must not use it

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

- rivastigmine, the active ingredient in Exelon Patch
- any of the other ingredients of Exelon 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 Exelon 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 Exelon 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 Exelon 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 Exelon Patch in children.

It is not known how Exelon Patch will affect children.

If you are not sure whether you should start using Exelon 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 including an irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or family history of low potassium or magnesium
- 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 Exelon 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 Exelon Patch that is in your body. A sudden change in your usual smoking habit can also change the effects of Exelon 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 Exelon 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

Use caution when taking Exelon together with medicinal products known to prolong the heart's electrical system (QT interval). This could be including drugs like quinidine, amiodarone, pimozide, halofantrine, cisapride, citalopram, mizolastin, moxifloxacin, erythromycin, chlorpromazine, levomepromazine, sulpiride, sultopride, amisulpride, tiapride, veralipride, haloperidol, droperidol, diphemanil, methadone, and pentamidine. Your doctor may also monitor your clinical condition as needed.

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

Always apply this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist, or healthcare provider if you are not sure.

Do not exceed the recommended dose prescribed by your doctor.

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 Exelon Patch

Every 24 hours, gently remove any existing Exelon patch before putting on a new one. See "How to remove Exelon 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 for example on the right side of your body one day, then on the left side the next day).

Consecutive patches can be applied to the same general anatomic area (e.g., if the first patch is applied on right upper arm, the next patch can be applied to left upper arm or to another spot on the right upper arm).

Before you apply Exelon 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.

A leaflet in the carton contains diagrams showing these locations. 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 Exelon Patch

Gently pull at one edge of the Exelon 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 Exelon Patch is more suitable for you. Treatment usually starts with one Exelon Patch 5 daily. After about four weeks of treatment the usual daily dose is Exelon Patch 10. If well tolerated, your doctor may increase the dose to Exelon 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 Exelon Patch at a time.

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

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

How to use it

Read the "How to use" leaflet carefully.

A "How to use" leaflet is enclosed in Exelon Patch cartons. This leaflet contains pictures

and instructions showing how to apply the patch properly.

How long to use it

Apply a new patch every day.

Exelon 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 Exelon 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 Exelon Patch or change your dose without talking with your doctor.

Switching from Exelon Capsules to Exelon Patch

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

NEVER take Exelon Capsules when using Exelon 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 Exelon 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 Exelon Patch 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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If your Exelon Patch falls off

If your Exelon Patch falls off, apply a new patch to the same site for the rest of the 24 hours. 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 Exelon 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
- seizures (fits or convulsions).

While you are using Exelon 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 Exelon that is in your body. A sudden change in your usual smoking habit can also change the effects of Exelon.

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 Exelon 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 Exelon Patch.

Exelon 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 Exelon Patch.

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

Exelon 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 Exelon 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
- anxiety
- 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, swelling at the application site
- increased sweating
- difficulty sleeping
- confusion
- mood changes such as feeling aggression, anxious, nervousness, depressed (sad mood)
- unusual 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
- blood in the stools or when vomiting gastric ulcer and 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 Exelon 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 Exelon 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. Exelon 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 Exelon 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

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

- Patch 5: the outside of the backing layer is beige and labelled with "AMCX" and "Exelon® Patch 5 (rivastigmine)"
- Patch 10: the outside of the backing layer is beige and labelled with "BHDI" and "Exelon® Patch 10 (rivastigmine)"
- Patch 15: the outside of the backing layer is beige and labelled with "CNFU" and "Exelon® Patch 15 (rivastigmine)"

Ingredients

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

- DL-alpha-tocopherol
- Acrylates copolymer
- Silicone oil (dimethicone 12500)
- Adhesive matrix (Durotak 387-2353 and Bio PSA Q7-4302)

Sponsor

Exelon is supplied in Australia by:
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