

# EXELON PATCH®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using EXELON PATCH?

EXELON PATCH contains the active ingredient rivastigmine. EXELON PATCH is used to treat adults with Alzheimer's disease.

For more information, see Section [1. Why am I using EXELON PATCH?](#) in the full CMI.

### 2. What should I know before I use EXELON PATCH?

Do not use if you have ever had an allergic reaction to EXELON PATCH or any of the ingredients listed at the end of the CMI. Do not use EXELON PATCH if you have a liver condition.

For more information, see Section [2. What should I know before I use EXELON PATCH?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with EXELON PATCH and affect how it works. This can include nicotine, medicines used to reduce pain or swelling, medicines to treat blood pressure, medicines used in surgical procedures and some others.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use EXELON PATCH?

- Apply ONE patch per day to one location of your body (upper arm, chest, upper back, or lower back). Press the patch firmly in place for at least 30 seconds ensuring it is flat and makes good contact with your skin. Read the "How to use" leaflet that came with EXELON PATCH. You must apply a new EXELON PATCH each day ensuring you remove the old one first.

More instructions can be found in Section [4. How do I use EXELON PATCH?](#) in the full CMI.

### 5. What should I know while using EXELON PATCH?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, surgeon, or pharmacist you visit that</li></ul>
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	<p>you are using EXELON PATCH.</p> <ul style="list-style-type: none"> <li>● Tell your doctor if you smoke.</li> <li>● Tell your doctor if you are pregnant or planning to become pregnant.</li> <li>● Tell your doctor if you are sick to the point of throwing up frequently or using the toilet a lot.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do NOT cut the patch or expose EXELON PATCH directly to heat for long periods of time.</li> <li>● Do NOT place the patch on wet, sticky, slippery, cut, or irritated skin or where the patch may be rubbed off by tight clothing.</li> <li>● Do NOT place the patch on an area of skin that has powder, lotion, oil, or moisturiser on it.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● EXELON PATCH may make you feel dizzy or tired and may impact your driving.</li> </ul>

<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● EXELON PATCH may make you feel dizzy or tired. Drinking alcohol may increase this effect.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>● Keep it in a cool, dry, place at room temperature (below 25°C).</li> <li>● Keep EXELON PATCH in the packet until it is time for you to apply it.</li> </ul>

For more information, see Section [5. What should I know while using EXELON?](#) in the full CMI.

## 6. Are there any side effects?

More common side effects include: feeling tired, sick, weak, or dizzy; headaches, diarrhoea, irritated/red skin where the patch was, decreased weight. More serious side effects may include seeing or hearing things that are not there, wheezing, trouble breathing, swelling of the lips/tongue, pain when going to the toilet, severe tummy pain, trouble controlling movement or balance, blood in poo or vomit, chest pain, yellow skin/eyes, feeling confused, persistent swelling/blistering on skin that spreads.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



# EXELON PATCH<sup>®</sup> (Ex-eh-lon)

**Active ingredient(s):** *rivastigmine* (RIV-a-STIG-mean)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using EXELON PATCH. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EXELON PATCH.**

**Where to find information in this leaflet:**

- [1. Why am I using EXELON PATCH?](#)
- [2. What should I know before I apply EXELON PATCH?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I apply EXELON PATCH?](#)
- [5. What should I know while applying EXELON PATCH?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using EXELON PATCH?

**EXELON PATCH contains the active ingredient rivastigmine.** EXELON PATCH is medicine that is known as a "cholinesterase inhibitor". This means that it increases the amount of a chemical known as "acetylcholine" in your brain. This chemical is a

"neurotransmitter", meaning it helps the brain send messages throughout your body.

**EXELON PATCH is used to treat a condition in adults known as Alzheimer's disease where damage is caused in the brain because there is a reduced number of cells that make these chemicals.**

**Alzheimer's disease can lead to problems remembering things, thinking clearly, and acting or behaving the way you normally would. Generally, these problems become worse over time. EXELON PATCH may help to reduce the symptoms and slow down the disease.**

## **2. What should I know before I apply EXELON PATCH?**

### **Warnings**

#### **Do not apply EXELON PATCH if:**

- you are allergic to rivastigmine, carbamates or any of the ingredients listed at the end of this leaflet.
- you have a liver condition.
- you have a history of skin reactions to adhesives or experienced a persistent rash, swelling or blistering of skin from previous EXELON PATCH doses.
- the expiry date printed on the back of the pack has passed or the pack shows signs of tampering.
- you are under 18 years of age.

## Check with your doctor if you:

- have difficulty going to the toilet.
- have, or have ever had a heart condition such as an irregular or slow heartbeat, QTc prolongation, a family history of QTc prolongation, torsade de pointes, or have low potassium or magnesium.
- have a stomach ulcer or history of stomach ulcers.
- have any breathing difficulties or history of respiratory disorders for example asthma.
- suffer from seizures (fits) or trembling.
- have a low body weight (less than 50 kilograms).
- are frequently unwell to the point of vomiting or going to the toilet a lot.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Skin reactions

EXELON PATCH contains a sticky material (adhesive) that your skin may react badly to. Your doctor may wish to monitor you if you develop a rash or irritated skin that does not resolve within 48 hours or starting or increases beyond the size of the patch itself. Your doctor in this instance may also consider switching you to the same medicine in capsule form (EXELON capsules) but only if your doctor is sure that you are not allergic to these medicines.



## **Gastrointestinal problems**

If your doctor prescribes a higher dose, you may experience an increase in nausea (feeling sick), vomiting (throwing up) and diarrhea leading to extreme weight loss. Your doctor may choose to monitor your weight closely, especially if it drops below 50 kilograms.

Additionally, your doctor may monitor you closely if you suffer from ulcers (sores) in your tummy or intestines (gut) since EXELON PATCH can make it worse, particularly if you are also taking some medicines that reduce swelling, pain, or fever.

## **Cardiovascular and respiratory problems**

Your doctor may monitor you if you have a heart condition (such as irregular or fast heartbeat) or a lung condition (such as asthma or a wheezy/chesty cough) as it may make this worse.

## **Movement problems**

Your doctor may wish to monitor you while using EXELON PATCH especially if you have a condition known as Parkinson's disease or suffer from seizures (fits) which makes it difficult to control body movement. EXELON PATCH may make these conditions worse.

## **Obstructions or blockages**

Your doctor may wish to monitor you if you have trouble doing a wee (obstruction) or have existing kidney damage.

## **Smoking**

- Nicotine which can be found in cigarettes (including patches to aid in quitting smoking) can affect how well EXELON PATCH works. Sudden changes to smoking habits
- may also affect EXELON PATCH.

## **Using EXELON PATCH while swimming, bathing or in the sun**

Bathing, swimming, and showering should not affect the patch; however, you should ensure that it does not rub off under your swimming costume.

Do not expose EXELON PATCH to direct sources of heat for long periods of time including the sun, fireplaces, heaters, saunas, and tanning beds.

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant, think you may be pregnant, or intend to become pregnant. It is not known whether using EXELON PATCH may affect your baby.

You should not breast-feed during treatment with EXELON PATCH. Talk to your doctor if you intend to breast-feed.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop. You may need to take different medicines or different amounts of your current medicines while you are using EXELON PATCH.

#### **Some medicines may interfere with EXELON PATCH and affect how it works.**

Your doctor may decide not to use EXELON PATCH or monitor your condition closely if you are taking some of the medicines below.

#### **Medicines that may affect EXELON PATCH include:**

- Medicines that relieve or stop nausea (feeling sick) such as metoclopramide may lead to stiff arms and legs or shaking hands that you cannot control.
- Medicines such as atenolol used to treat high blood pressure, angina or other heart problems known as "beta blockers" which may cause fainting or loss of consciousness.
- Medicines that are used in surgery to relax your muscles such as bethanechol.
- Other medicines with similar effects (cholinomimetic agents) or with anticholinergic medications (such as

medicines used to relieve stomach cramps or spasms or to prevent travel sickness).

- Medicines for a variety of conditions that affect the heart's electrical system ("QT interval") which can include medicines like quinidine, amiodarone, pimozide, halofantrine, cisapride, citalopram, mizolastin, moxifloxacin, and erythromycin.

EXELON may also be impacted by nicotine. Talk to your doctor if you smoke.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EXELON PATCH.**

## **4. How do I apply EXELON PATCH?**

### **How to apply EXELON PATCH**

- Read the "How to use" leaflet that came with EXELON PATCH carefully. This leaflet will contain the pictures and instructions on how to apply EXELON PATCH correctly. EXELON PATCH can only be placed on certain areas of the body including the legs, arms, chest, abdomen and back that is clean, dry, and hairless (see section "Things you should not do").
- Press the patch firmly in place for at least 30 seconds ensuring it is flat and makes good contact with your skin.
- EXELON PATCH should be applied to a different area of skin each time you use a new patch for example on the right side of your body one day and the left side on the next day. You can apply a patch to the same

general area on the body but avoid placing it directly where the last one was for at least a week.

## **Where to apply EXELON PATCH**

- Apply only ONE patch per day to only ONE of the following
- locations of 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
- Avoid wearing tight clothing over the top as your patch
- may come off.

## **How to remove EXELON PATCH**

- Gently and slowly lift the patch at one edge to remove it from the skin.
- If there is any residue from the patch on the skin, wash the area with soap and warm water gently. Do not use rubbing alcohol, nail polish remover or anything similar since it may cause irritation to the skin.
- Wash your hands with soap and water after you remove the patch.
- If any of the residue meets your eyes, then you should rinse them immediately with water and seek medical advice if your eyes become red and irritated without improving.

## **When to apply EXELON PATCH**

- A new EXELON PATCH should be applied every 24 hours.
- Before you apply a new EXELON PATCH, make sure you remove the old one first as having more than one patch at a time on your body can be dangerous. See section "how to remove EXELON PATCH".

## **If you forget to apply EXELON PATCH**

**If you have forgotten to apply your EXELON PATCH when you should have, apply a new one immediately. Make sure you remove the old patch first.**

**Do not apply two patches to make up for the dose you missed. This may increase the chances of unwanted side effects.**

- Tell your doctor if it has been more than 3 days since you
- applied a new patch. Do not apply a new patch until
- you talk to your doctor first as they may need to restart
- you on a lower dose.

## **When switching from Exelon capsules to EXELON PATCH**

You may have previously been taking EXELON in a capsule form before your doctor switched you to the EXELON PATCH.

Never take EXELON capsules if you are also taking EXELON PATCH. You should return unused EXELON capsules to the Pharmacy (see section "Getting rid of any unwanted medicine")

## **How long do I use EXELON PATCH**

You must continue to use it for as long as your doctor tells you to.

## **How much EXELON PATCH should be used**

Your doctor will tell you what dose you will take. Usually, you will start on one EXELON PATCH 5 each day. Your doctor may change your dose over time depending on how you respond.

If your doctor changes your dose, you will still only need to apply one patch per day.

## **If your EXELON PATCH falls off**

Do not reapply the used patch.

If your patch falls off before you would normally need to place a new patch on, then you can apply a new patch for the rest of the 24-hour period. You must then replace with a new patch the next day at the same time as usual.

## **If you apply too much EXELON PATCH**

If you think that you applied more patches than you should or used another patch without removing the old one, or accidentally swallowed some of the contents of the patch,

### **You should immediately:**

- remove any patches of EXELON from your skin
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning. You may feel sick, dizzy, faint or see and/or hear things that are not there.**

## **5. What should I know while using EXELON PATCH?**

### **Things you should do**

- Keep your appointments so your progress can be checked.
- Remind any doctor, dentist, surgeon, or pharmacist you visit that you are using EXELON PATCH.
- Tell your doctor if you smoke.
- Tell your doctor if you are pregnant or planning to become pregnant.



- Tell your doctor if you are sick to the point of throwing up frequently or are going to the toilet regularly as this may cause extreme weight loss and dehydration.

## **Call your doctor straight away if you:**

- Have irritated, red skin or blisters that are swelling and spreading.
- Have chest pain, difficulty breathing, swallowing, or are wheezing.
- Have strong tummy pain, blood in stools or vomit.
- Feel confused or are not thinking or seeing clearly.
- Have difficulty speaking, moving, or behaving as you normally would.
- Have yellow eyes or skin.
- Difficulty controlling body movement or bodily functions.

## **Things you should not do**

- Do NOT stop taking the medicine suddenly without talking to your doctor first.
- Do NOT give this medicine to someone else.
- Do NOT cut the Exelon Patch.
- Do NOT place the patch on wet, sticky, slippery or irritated skin.
- Do NOT place the patch on an area of skin that has powder, lotion, oil, or moisturiser on it.
- Do NOT place the patch on an area of skin that is cut or has open wounds.

- Do NOT place the patch where it may be rubbed off by tight clothing.
- Do NOT expose the patch to heat for long periods of time including sunlight, saunas, tanning beds, heaters, or fireplaces.

## **Driving or using machines**

Your doctor will tell you whether you are able to drive or use machines.

EXELON PATCH may make you feel dizzy or tired. Do NOT drive or use machines or tools if you feel dizzy or tired as you may not be able to think clearly.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

EXELON PATCH may make you feel dizzy or tired. Alcohol may increase this effect.

## **Looking after your medicine**

- Make sure you keep EXELON PATCH in the packet until it is time for you to apply it.
- Keep it in a cool, dry, place at room temperature (below 25°C).
- Do not store EXELON PATCH in the bathroom or near the sink.
- Do not leave EXELON PATCH sitting in the car or on a windowsill.

If EXELON PATCH gets wet or too hot, it might not work the way it is supposed to.

**Keep it where young children cannot reach it.**

EXELON PATCH should be kept in a locked cupboard at least 1.5 metres off the ground.

## **When to discard your medicine**

After the patch has been removed from your body, fold the patch in half with the sticky sides on the inside and press them together. Place the patch in the original sachet and discard where children cannot access it such as your outside bins. Wash your hands with soap and water after doing this.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. You should also return EXELON capsules if you were using these prior to your doctor switching you to EXELON PATCH

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Tummy problems</b></p> <ul style="list-style-type: none"> <li>• Indigestion</li> <li>• Mild tummy pain or discomfort</li> <li>• Loss of appetite or weight loss</li> <li>• Diarrhoea</li> </ul> <p><b>Skin problems:</b></p> <ul style="list-style-type: none"> <li>• Redness, itching or irritation where a patch has just been</li> <li>• Increased sweating</li> </ul> <p><b>General wellness:</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Feeling sick, nauseous</li> <li>• Feeling tired or weak</li> <li>• Trouble sleeping</li> <li>• Feeling extremely thirsty</li> </ul> <p><b>Mood or behavioural changes:</b></p>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p> <p>These side effects usually happen at the start of treatment when the dose is being increased.</p> <p>Women are more likely than men to get some side effects (e.g., nausea, vomiting, loss of appetite, weight loss).</p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Feeling anxious or nervous</li> <li>● Feeling down</li> <li>● Feeling angry, irritated</li> <li>● Feeling sleepy</li> <li>● Being more active than usual</li> <li>● Nightmares</li> </ul> <p><b>Changes to toilet habits:</b></p> <ul style="list-style-type: none"> <li>● Going to the toilet accidentally or more frequently.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Skin problems:</b></p> <ul style="list-style-type: none"> <li>● Yellowing of skin or whites of the eyes</li> <li>● Blisters or swelling of the skin that are spreading</li> <li>● Persistent hives or skin rash</li> <li>● Persistent swelling and redness of the skin</li> </ul>	<p><b>Tell your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of the following</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Heart problems:</b></p> <ul style="list-style-type: none"> <li>• Chest pain</li> <li>• Unusual changes to heartbeat (beating very fast or slow)</li> <li>• High blood pressure</li> </ul> <p><b>Tummy problems:</b></p> <ul style="list-style-type: none"> <li>• Blood in stool or vomit</li> <li>• Strong pain in your tummy</li> </ul> <p><b>Mood or behavioural changes:</b></p> <ul style="list-style-type: none"> <li>• Feeling confused</li> <li>• Feeling suspicious or strange thinking patterns</li> <li>• Seeing or hearing things that are not there</li> <li>• Feeling dizzy, spacey, or faint</li> <li>• Not seeing properly</li> <li>• Feeling extremely sad (depressed)</li> </ul> <p><b>Movement problems:</b></p> <ul style="list-style-type: none"> <li>• Uncontrollable trembling</li> <li>• Fits (seizures)</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Loss of co-ordination, balance or difficulty speaking</li> <li>● Stiff, painful arms and legs</li> </ul> <p><b>Breathing problems:</b></p> <ul style="list-style-type: none"> <li>● Swelling of the tongue</li> <li>● Difficulty breathing or swallowing</li> <li>● Wheezing</li> </ul> <p><b>Kidney problems:</b></p> <ul style="list-style-type: none"> <li>● Very dark wee</li> <li>● Going to the toilet frequently</li> <li>● Pain when you wee</li> <li>● Dehydration</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What EXELON PATCH contains

Each EXELON PATCH 5, PATCH 10 or PATCH 15 contains 9 mg, 18 mg, or 27 mg of the active ingredient (rivastigmine) respectively.

<b>Active ingredient (main ingredient)</b>	Rivastigmine
<b>Other ingredients (inactive ingredients)</b>	DI-alpha-tocopherol Acrylates copolymer Silicone oil (dimethicone 12500) Adhesive matrix (Durotak 387-2353 and Bio PSA Q7-4302)
<b>Potential allergens</b>	Carbamate



**Do not take this medicine if you are allergic to any of these ingredients.**

## **What EXELON PATCH looks like**

Exelon Patch is available in three 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)" - AUST R 133422
- Patch 10: the outside of the backing layer is beige and labelled with "BHDI" and "Exelon® Patch 10 (rivastigmine)" - AUST R 133428
- Patch 15: the outside of the backing layer is beige and labelled with "CNFU" and "Exelon® Patch 15 (rivastigmine)" - AUST R 222604

## **Who distributes EXELON PATCH**

Exelon is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Web site: [www.novartis.com.au](http://www.novartis.com.au)

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