

EXELON®

Consumer Medicine Information (CMI) summary

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

1. Why am I taking EXELON?

EXELON contains the active ingredient rivastigmine (present as rivastigmine hydrogen tartrate). EXELON is used to treat Alzheimer's disease. For more information, see Section [1. Why am I taking EXELON?](#) in the full CMI.

2. What should I know before I take EXELON?

Do not use if you have ever had an allergic reaction to rivastigmine, carbamate derivatives or any of the ingredients listed at the end of the CMI. EXELON capsules contain tartrazine, residual sulfites, phenylalanine and carbamate traces. Do not take EXELON if you have a liver condition or have previously suffered a severe skin reaction from taking EXELON in a patch form (EXELON PATCH).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take EXELON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EXELON and affect how it works. This can include nicotine, medicines used to reduce pain or swelling, medicines for nausea, 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 take EXELON?

- One capsule is taken twice each day.
- Swallow the EXELON capsule whole with a glass of liquid; once with your morning meal and once with your evening meal.

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

5. What should I know while taking EXELON?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, surgeon, anaesthetist, or pharmacist you visit you are taking EXELON.• 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 using the toilet a lot.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly or give this medicine to someone else.
Driving or taking machines	<ul style="list-style-type: none">• EXELON may make you feel tired or dizzy and may impact your driving.
Drinking alcohol	<ul style="list-style-type: none">• EXELON may make you feel dizzy or tired. Drinking alcohol may increase this effect.

Looking after your medicine	<ul style="list-style-type: none"> • Keep it in a cool, dry, place at room temperature (below 25°C) until it is time to take them. • Keep it in the original packaging
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For more information, see Section [5. What should I know while taking EXELON?](#) in the full CMI.

6. Are there any side effects?

More common side effects include: feeling tired, sick, weak, annoyed, restless, anxious or dizzy; headaches, throwing up, tummy discomfort/cramps/pain; feeling shaky or trembling, increased sweating, or saliva, diarrhoea, weight loss, loss of appetite, nightmares. More serious side effects include: trouble breathing, wheezing, rash/blisters/hives that are spreading on your body and face, chest pain/changes to heartbeat, yellow skin or eyes, trouble speaking, balancing, walking or uncontrolled movement/shaking, trouble or pain when going to the toilet, dehydration, feeling very faint/fainting, blood in stools or vomit.

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[®] (Ex-eh-lon)

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking EXELON?

EXELON contains the active ingredient rivastigmine (present as rivastigmine hydrogen tartrate). EXELON is a 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 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 may help to reduce the symptoms and slow down the disease.

2. What should I know before I take EXELON?

Warnings

Do not take EXELON if:

- You are allergic to rivastigmine, carbamates, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- You have a liver condition.
- You have had a skin reaction (such as blisters, increasing skin inflammation, swelling) from using EXELON in a patch form previously that spread beyond the size of the patch and did not improve

within 48 hours after removal of the patch from your skin.

- 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.

Symptoms of an allergic reaction may include wheezing or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; rash, blisters or hives on the skin, eyes, tongue, or face.

Check with your doctor if you:

- have difficulty going to the toilet (doing a wee) or a kidney problem.
- have, or have ever had heart a condition such as an irregular or fast/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

Your doctor may have switched you from EXELON PATCH to EXELON in a capsule form. Your doctor will confirm that you are not allergic to this before starting treatment with capsules.

This is because EXELON PATCH contains a sticky material (adhesive), which your skin may have reacted badly to while you were applying EXELON PATCH. If that is the case, your doctor may wish to monitor you closely while you are taking EXELON capsules in case the same thing happens again.

You may not be able to take EXELON at all in any form.

Gastrointestinal problems, weight loss

When commencing treatment, or if your doctor prescribes a higher dose, you may experience an increase in nausea (feeling sick), vomiting (throwing up) and diarrhoea leading to extreme weight loss and dehydration. Your doctor may choose to monitor your weight closely, especially if it drops below 50 kilograms or you weigh less than that already.

Additionally, your doctor may monitor you closely if you suffer from ulcers (sores) in your tummy or intestines (gut) since EXELON 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. Your doctor will want to know your family history on this.

Movement problems

Your doctor may wish to monitor you while taking EXELON especially if you have a condition known as Parkinson's disease or suffer from seizures (fits) or tremors which makes it difficult to control body movement. EXELON 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 works. Sudden changes to smoking habits may also affect EXELON.

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 taking EXELON may affect your baby.

You should not breast-feed during treatment with EXELON. 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.

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

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

Medicines that may affect EXELON 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.

4. How do I take EXELON?

How much to take

- Your doctor will decide how much EXELON you will need to take.
- Follow the instructions provided and take EXELON until your doctor tells you to stop.
- The usual starting dose is a 1.5 mg capsule taken twice a day. Depending how your body responds to this, your doctor may change this dose gradually up to a 6 mg capsule taken twice a day.

When to take EXELON

- EXELON should be taken at about the same time each day to help you remember.
- Take one EXELON capsule with your morning meal and one capsule with your evening meal.

How to take EXELON

- Swallow EXELON capsules whole with a glass of water or other liquid with your morning and evening meals.
- Do not crush, open, or break the capsules.

How long to take EXELON

- Take EXELON as directed by your doctor for as long as your doctor tells you to.

If you forget to take EXELON

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

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

If it has been more than three days since you last had EXELON, you will need to talk to your doctor before you take any more EXELON as they may want to change your dose to the lowest dose. If you have a caregiver,

tell them as well if it has been more than three days since you last had EXELON.

If you use too much EXELON

If you think that you have taken too much EXELON, you may need urgent medical attention.

You should immediately:

- 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.

Some of the symptoms of an overdose may include severe nausea (feeling sick), vomiting (being sick), diarrhoea, hallucinations, high blood pressure, slow heartbeat, and fainting.

5. What should I know while taking EXELON?

Things you should do

- Keep your appointments so your progress can be checked. If you have a caregiver, bring them to the appointments.
- Remind any doctor, dentist, surgeon, anaesthetist, or pharmacist you visit that you are taking EXELON.

- 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/hives that are swelling and spreading. You may be allergic.
- Become pregnant or think you may be pregnant.
- Have crushing 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 other 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EXELON affects you.

EXELON may make you feel dizzy or tired, especially if your doctor starts to increase your dose or you have just started on treatment. Do not drive, use machines, or perform any other task requiring your attention if you are feeling dizzy or tired.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Store the capsules in the original carton at room temperature (below 25°C).

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

Continue taking EXELON for as long as your doctor tells you. When the EXELON capsules are all gone, place the empty carton/blister in outside rubbish.

Getting rid of any unwanted medicine

If your doctor tells you not to take any more EXELON or it is out of date, take any that you have left to any pharmacy for safe disposal.

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
General well-being <ul style="list-style-type: none">• Feeling tired or weak• Feeling dizzy	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Feeling anxious, sad, angry, or annoyed • Feeling restless, hyperactive • Feeling sick or throwing up • Headache • Increased sweating or saliva • Nightmares, difficulty sleeping • Weight loss <p>Movement problems</p> <ul style="list-style-type: none"> • Feeling shaky • Trembling <p>Kidney problems</p> <ul style="list-style-type: none"> • Unable to control when you need to do a wee (incontinence) <p>Tummy problems</p> <ul style="list-style-type: none"> • Unable to control when you need to have a bowel movement • Minor tummy pain, discomfort, or cramps • Diarrhoea 	<p>Tell your doctor if you do not feel well while taking EXELON.</p> <p>Women are more likely than men to get some side effects (e.g., nausea, vomiting, loss of appetite, weight loss).</p>

Less serious side effects	What to do
Skin problems <ul style="list-style-type: none"> • Rash, feeling itchy 	

Serious side effects

Serious side effects	What to do
General well-being <ul style="list-style-type: none"> • Feeling very sad (depression) Signs of an allergic reaction: <ul style="list-style-type: none"> • Trouble breathing, wheezing • Hives, blisters, or rash that is swelling or spreading on your body, face, tongue, face, or lips Heart problems: <ul style="list-style-type: none"> • Chest pain/crushing chest pain (signs of a heart attack) • Unusually fast, slow, or irregular heartbeat Circulation problems:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul style="list-style-type: none"> • Loss of co-ordination/ balance • Difficulty speaking (possible signs of stroke) • Severe confusion/ hallucinations <p>Tummy problems:</p> <ul style="list-style-type: none"> • Blood in vomit or stools • Severe tummy pain • Ulcers (sores) in tummy or gut <p>Liver problems:</p> <ul style="list-style-type: none"> • Yellow eyes or skin • Severe nausea, weakness, and tiredness with loss of appetite <p>Kidney problems:</p> <ul style="list-style-type: none"> • Pain when you wee or going to the toilet more than normal (signs of a urinary tract infection) • Feeling very thirsty (dehydration) along with dizziness or fainting. • Very dark wee <p>Movement problems:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> • Stiff limbs, trembling hands • Seizures (fits) • Falls • Changes to walking • Uncontrolled movement 	

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. 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.

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

What EXELON contains

Active ingredient (main ingredient)	Rivastigmine (as hydrogen tartrate)
Other ingredients (inactive ingredients)	Magnesium stearate Hypromellose Colloidal anhydrous silica Microcrystalline cellulose Gelatin Red iron oxide (CI77491) Yellow iron oxide (CI77492) Titanium dioxide Printing ink (containing red iron oxide, titanium dioxide, and shellac)
Potential allergens	Contains tartrazine, sulfites, phenylalanine and carbamate traces.

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

What EXELON looks like

EXELON capsules are available in four strengths in packs of 56 capsules:

- EXELON 1.5 mg: yellow capsules printed with "EXELON" and "1.5 mg" in red (AUST R 71445).
- EXELON 3.0 mg: orange capsules printed with "EXELON" and "3 mg" in red (AUST R 71446).
- EXELON 4.5 mg: red capsules printed with "EXELON" and "4.5 mg" in white (AUST R 71447).
- EXELON 6.0 mg: orange and red capsules printed with "EXELON" and "6 mg" in red (AUST R 71448).

Who distributes EXELON

EXELON capsules are supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone 1 800 671 203

Web site: www.novartis.com.au

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