

Package Leaflet: Information for the User

Eldepryl® 5 mg Tablets

selegiline hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Eldepryl is and what it is used for
2. What you need to know before you take Eldepryl
3. How to take Eldepryl
4. Possible side effects
5. How to store Eldepryl
6. Contents of the pack and other information

1. What Eldepryl is and what it is used for

Eldepryl contains the active substance selegiline hydrochloride. Eldepryl is a monoamine oxidase-B inhibitor, and is used in the treatment of Parkinson's disease. Eldepryl may be taken alone in the early stages of your condition, delaying the need for the addition of other medicines. Eldepryl however can also be used in conjunction with other treatments such as levodopa to reduce the on-off symptoms or uncontrolled movements you may experience. This happens especially when the effects of the other treatments are wearing-off.

Your doctor will explain why this medicine has been chosen for you.

2. What you need to know before you take Eldepryl

Do not take Eldepryl

- if you are allergic (hypersensitive) to selegiline hydrochloride or any of the other ingredients of Eldepryl (listed in section 6)
- if you are taking any antidepressants (see Other medicines and Eldepryl). Antidepressants should be stopped a number of weeks before taking Eldepryl, speak to your doctor for further advice
- if you are taking a group of medicines known as sympathomimetics which are used to treat for example asthma, allergies or problems with your heart
- if you are taking an opioid painkiller called pethidine
- if you are taking any monoamine oxidase inhibitors e.g. the antibiotic linezolid
- if you suffer from stomach or duodenal ulcers.

Warnings and precautions

Talk to your doctor or pharmacist before using Eldepryl if any of the following applies to you:

- if you have uncontrolled high blood pressure, chest pain (angina), the sensation of feeling your heartbeat (palpitations) or an abnormal or erratic heartbeat (arrhythmia)
- if you have kidney or liver problems
- if you suffer from stomach ulcers or bleeding from your gut
- if you are being treated for any mental illness
- if you are already taking a medicine called Levodopa. Your doctor may need to monitor you closely and alter your dose
- if you are going to have surgery as Eldepryl may interfere with some of the medicines used as part of a general anaesthetic
- if you or your family notice that you are developing any unusual behaviours or compulsions (such as an unusual urge for gambling, binge eating, compulsive shopping or increased sexual urges) while you are taking Eldepryl.

Children

Eldepryl should not be given to children.

Other medicines and Eldepryl

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular it is important that you tell your doctor if you are taking any of the following:

- Dopamine or levodopa (used to treat Parkinson's disease)
- any type of antidepressant e.g. citalopram, escitalopram, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline, protriptyline and fluoxetine cannot be taken with Eldepryl. You should stop taking fluoxetine at least 5 weeks before taking Eldepryl, your doctor will give you further advice. Eldepryl should be stopped at least 14 days before taking fluoxetine
- a group of medicines known as sympathomimetics which are used to treat asthma, nasal congestion, allergies or problems with your heart
- oral contraceptives (The 'pill', other forms of contraception should be discussed with your doctor)
- an opioid painkiller called Pethidine
- a pain killer called Tramadol
- medicines to treat anxiety or sleep problems
- a group of medicines known as monoamine oxidase inhibitors used to treat depression
- the antibiotic linezolid
- medicines to treat heart problems (e.g. digitalis) as you may need more frequent check-ups with your doctor
- medicines to thin the blood (anticoagulants) as you may need more frequent check-ups with your doctor.

Eldepryl needs a period of time to be completely removed from the body before starting certain other medicines. Please talk to your doctor for advice if you are thinking about starting other medication.

Eldepryl with food, drink and alcohol

You may take Eldepryl with food and drink.

Alcohol should be avoided whilst you are taking Eldepryl. Your doctor may recommend that you avoid certain foods containing tyramine, such as mature cheese, broad beans, yeast extracts or fermented soya bean products.

Pregnancy and breast-feeding

- You should not take Eldepryl if you are pregnant, planning to become pregnant or if you think you may be pregnant.
- You should not take Eldepryl if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Eldepryl may make you feel dizzy therefore your ability to drive or operate machinery may be affected. If you experience this side effect then do not drive, use tools or operate machinery.

3. How to take Eldepryl

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is 5 - 10mg Eldepryl each day.

- Eldepryl can be taken as a single daily dose in the morning, or the prescribed daily dose taken in two parts, half dose in the morning and half dose at lunchtime. If you take your tablets in the evening or before going to bed they may keep you awake at night.
- Your doctor will tell you how long you should continue to take this medicine.

If you take more Eldepryl than you should

Your doctor has carefully chosen the correct dosage for you so do not take more than the prescribed dose. However, if you accidentally take too much Eldepryl immediately contact your doctor or contact your nearest hospital casualty department. Symptoms of an overdose include agitation, feeling irritable, restless or tired, severe headache, feeling faint, shaking, high or low blood pressure, difficulty breathing, shortness of breath, experiencing sensations, visions or sounds which are not real

(hallucinations), dizziness, fast irregular heartbeat, chest pain, severe muscle spasms, fever, excessive sweating, loss of consciousness and fits.

If you forget to take Eldepryl

If you forget to take a dose, take a dose as soon as you remember, but do not take more than the recommended dose every 24 hours. Do not take a double dose to make up for a forgotten dose.

If you stop taking Eldepryl

Do not stop taking Eldepryl unless told to do so by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If someone else takes your medicine

If someone else has swallowed any of your medicine, contact your nearest hospital casualty department or tell a doctor immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)

- Sleep disturbances, confusion, experiencing situations, visions or sounds, which are not real (hallucinations)
- excessive, uncontrolled movements
- feeling sick
- slow heart beat (bradycardia)
- headache, a feeling of dizziness or 'spinning'
- abnormal liver tests due to increase in liver enzymes.

Uncommon (may affect up to 1 in 100 people)

- Changes in mood
- problems sleeping
- fast heart beat
- dry mouth.

Rare (may affect up to 1 in 1,000 people)

- Erratic or irregular heart beat
- skin reactions or irritation
- feeling agitated
- the need to urinate frequently, the sudden lack of control over urination or the lack of ability to urinate (micturition disorders)
- low blood pressure leading to a feeling of light-headedness or dizziness, particularly when standing up.

Not Known (frequency cannot be estimated from the available data)

- Unusual behaviours and compulsions (such as an unusual urge for gambling, binge eating, compulsive shopping or increased sexual urges)
- difficulty passing urine.

If the effects persist, or are causing you a lot of discomfort talk with your doctor.

Side effects when Eldepryl is used with levodopa

When Eldepryl is taken with levodopa this may increase the side-effects of levodopa such as:

- confusion, experiencing situations, visions or sounds, which are not real (hallucinations), feeling agitated or restlessness
- erratic or irregular heartbeat
- low blood pressure leading to a feeling of light-headedness or dizziness, particularly when standing up
- excessive, uncontrollable movements after taking your medicine.

These effects will usually stop when the amount of levodopa you are taking is reduced.

Talk to your doctor about reducing the dose if you experience any of these effects.

If you feel unwell after taking Eldepryl, tell your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: + 353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ELDEPRYL

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.
- Do not store above 25 °C. Keep the container tightly closed. Store in the original container.
- If your doctor decides to stop treatment, return any left-over medicine to your pharmacist. Only keep it if your doctor tells you to.

6. FURTHER INFORMATION

What Eldepryl contains

Each tablet contains 5 mg of the active ingredient, Selegiline hydrochloride.

The other ingredients are: mannitol, maize starch, microcrystalline cellulose, povidone and magnesium stearate.

What Eldepryl looks like and contents of the pack

Eldepryl Tablets are white or almost white, round, convex uncoated tablets having a single scoreline on one face. Eldepryl Tablets are available in packs of 100 tablets.

Manufacturer

Orion Corporation, FI-02200 Espoo, Finland or Orion Corporation, Orion Pharma, Joensuukatu 7, FI-24100 Salo, Finland.

Parallel Product Authorisation number: PPA 465/304/1

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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