

PACKAGE LEAFLET: INFORMATION FOR THE USER

Eldepryl 5 mg Tablets Eldepryl 10 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
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1. WHAT ELDEPRYL IS AND WHAT IT IS USED FOR

Eldepryl is available as a 5 mg and 10 mg Tablet. 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 this medicine (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 pethidine or any other opioid painkillers such as codeine, tramadol or buprenorphine
- if you are taking any monoamine oxidase (MAO) inhibitors e.g. the antibiotic linezolid
- if you are taking any medicines for migraine e.g. sumatriptan, naratriptan, zolmitriptan and rizatriptan

- if you are taking any sympathomimetic medicines e.g. medicines used in the treatment of asthma or to relieve nasal congestion
- if you suffer from stomach or duodenal ulcers
- if you suffer from a movement or muscle disorder not connected to Parkinson's disease.

Taking Eldepryl with Levodopa

Do not take Eldepryl together with Levodopa if you suffer from any of the following conditions:

- major heart or blood vessel problems (cardiovascular disease)
- chest pain (angina)
- high blood pressure (arterial hypertension)
- an erratic or fast heartbeat (e.g. tachycardia or arrhythmias)
- an overactive thyroid gland (hyperthyroid disease)
- an eye condition called narrow angle glaucoma
- a tumour of your adrenal gland (phaeochromocytoma) or prostate (prostatic adenoma)
- major mental health problems (e.g. schizophrenia or advanced dementia).

Warnings and Precautions

Talk to your doctor or pharmacist before taking 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 are being treated for any mental illness, anxiety or sleep problems
- if you have a history of stomach ulcers
- if you are already taking a medicine called Levodopa as it can cause agitation and uncontrollable movements. 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 have a history of any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour). See section 4.

The use of Buprenorphine together with Eldepryl can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and 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:

- amantadine, dopamine or levodopa (used to treat Parkinson's disease)
- any type of antidepressant e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline and protriptyline cannot be taken with Eldepryl

- pethidine or any other opioid painkillers such as codeine, tramadol or buprenorphine cannot be taken with Eldepryl. These medicines may interact with Eldepryl and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- the antibiotic linezolid cannot be taken with Eldepryl
- if you are taking any sympathomimetic medicines e.g. medicines used in the treatment of asthma or to relieve nasal congestion - these medicines cannot be taken with Eldepryl
- any medicines for migraine e.g. sumatriptan, naratriptan, zolmitriptan and rizatriptan cannot be taken with Eldepryl
- medicines for high or low blood pressure
- medicines for mood or mental illness
- medicines to treat anxiety, sleep problems or to relax the gut muscles (medicines that act on the central nervous system)
- medicines used as part of an anaesthetic
- 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
- HRT (hormone replacement therapy)
- altretamine (used to treat ovarian cancer)
- oral contraceptives (The 'pill', other forms of contraception should be discussed 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, Bovril, 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, drowsy or slow your reactions, therefore your ability to drive or operate machinery may be affected. If you experience these side effects then do not drive, use tools or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

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.

Your doctor will normally start you on a dose of 10 mg Eldepryl each day.

This may be taken either as one 10 mg or two 5 mg tablets.

- 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.

Make sure you ask your pharmacist if the label on your medicine does not tell you how to take Eldepryl.

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, shaking, high or low blood pressure, difficulty breathing, shortness of breath, experiencing situations, 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.

Very Common (*may affect more than 1 in 10 people*)

- Sore mouth and swollen gums (stomatitis).

Common (*may affect up to 1 in 10 people*)

- Difficulty controlling your movements or loss of balance (dyskinesias, akinesia, bradykinesia), fall
- slow heart beat (bradycardia)
- dizziness, feeling faint, headache, shaking
- sleep disorders, confusion, experiencing situations, visions or sounds which are not real (hallucinations)
- feeling down (depressed)
- high or low blood pressure
- abnormal liver tests due to increase in liver enzymes
- feeling sick, constipation, diarrhoea, mouth ulcers
- blocked nose, sore throat
- back pain, joint pain (arthralgia), muscle cramps
- tiredness
- ear disorders giving the sensation of dizziness (vertigo)
- excessive sweating.

Uncommon (*may affect up to 1 in 100 people*)

- Chest pain (angina pectoris), irritability, swelling of the ankles
- irregular, erratic or fast heartbeat, the sensation of feeling your heart beat (palpitations)
- problems sleeping, strange dreams, feeling anxious or agitated, changes in mood, altered mental state / loss of contact with reality (psychoses)
- shortness of breath (dyspnoea)
- blurred vision
- low blood pressure leading to a feeling of light-headedness particularly when standing up (orthostatic hypotension)
- problems starting, passing and stopping urination or altered frequency of urination (micturition disorders)
- abnormal liver tests due to increase in liver enzymes (transient rise of serum alanine aminotransferase (ALAT))
- muscle weakness (myopathy)
- low level of white blood cells (leucocytopenia) and platelets (thrombocytopenia) in the blood which may increase the risk of bleeding, bruising or infections
- loss of appetite
- sore throat (pharyngitis), dry mouth

- hair loss, blisters or spots on skin.

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

- Low blood pressure leading to a feeling of light-headedness, dizziness or fainting, particularly when standing up (postural hypotension)
- skin reactions.

Not Known (*frequency cannot be estimated from the available data*) However these events can be considered to be very rare

- Hypersexuality (altered sexual interest and behaviour of significant concern to the patient or to others)
- unusual urges and/or behaviours (such as excessive gambling or other behaviours)
- inability or difficulty passing urine.

Side effects when Eldepryl is used with Levodopa

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

- excessive, uncontrollable movements after taking your medicine
- confusion, hallucinations, problems sleeping, agitation, feeling restless
- feeling your heartbeat (palpitations), irregular, erratic heartbeat, chest pain, swollen ankles and shortness of breath
- a feeling of sickness, dizziness, feeling faint, dry mouth, loss of appetite and problems passing urine
- low blood pressure leading to a feeling of light-headedness, particularly when standing up
- hypersexuality (altered sexual interest and behaviour of significant concern to the patient or to others)
- low level of white blood cells (leucocytopenia) and platelets (thrombocytopenia) in the blood which may increase the risk of bleeding, bruising or infections and temporary liver problems
- headache, skin reaction and loss of hair.

These side 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.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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. Your medicine could harm children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store your tablets at a temperature below 25°C, in a dry safe place. Tablets provided in plastic bottles should be kept in the container with the lid tightly closed and tablets provided in blister packs should be stored in the original carton, in order to protect them from moisture. If your doctor decides to stop treatment, return any left-over medicine to your pharmacist. Only keep it if your doctor tells you to.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Eldepryl contains

The active substance is selegiline hydrochloride. The tablets contain either 5 mg or 10 mg of the active ingredient.

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 in colour. Eldepryl 5 mg Tablets are available in a bottle of 100 tablets or blister-packs of 30, 50, 60 or 100 tablets. Eldepryl 10 mg Tablets are available in a bottle of 50 or 100 tablets or blister-packs of 30, 50, 60 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation, Orionintie 1,
FIN-02200 Espoo, Finland.

Manufacturer

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Joensuunkatu 7
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (UK) Limited, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA

This leaflet was last revised in March 2021.

For information on Parkinson's disease and help available please contact:
Parkinson's UK, 215 Vauxhall Bridge Road, SW1V 1EJ