ELDEPRYL™

Selegiline hydrochloride 5 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about ELDEPRYL tablets. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ELDEPRYL tablets against the benefits the medicine is expected to have for you.

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 ELDEPRYL is used for

ELDEPRYL tablets are used to treat the symptoms of Parkinson's disease. This is a disease of the brain that affects movement.

People with Parkinson's disease do not have enough nerve cells in the part of the brain that controls movement. These nerve cells produce a substance called dopamine. It is a lack of dopamine which causes problems with movement.

ELDEPRYL tablets keep dopamine around longer, helping with difficulties in movement.

Before you take it

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

When you must not take it

Do not take ELDEPRYL tablets if:

- 1. you have ever had an allergic reaction to:
- medicines containing selegiline
- any of the ingredients listed at the end of this leaflet.
- you have taken or are taking antidepressants known as selective serotonin reuptake inhibitors (SSRIs) such as Prozac® (fluoxetine), Aropax® (paroxetine) or Zoloft® (sertraline) within the last five weeks.
- you are taking antidepressants known as serotonin noradrenaline reuptake inhibitors (SNRIs) such as Efexor-XR® (venlafaxine), Pristiq® (desvenlafaxine) and Cymbalta® (duloxetine).
- you are taking pethidine (a strong pain killer) or other opiates (check with your doctor or pharmacist). Serious side effects could occur if you start to take ELDEPRYL tablets at the same time as these medicines.
- you are taking antidepressants known as monoamine oxidase inhibitors (MAOIs) such as Aurorix® (moclobemide),

Nardil® (phenelzine) or Parnate® (tranylcypromine) or have taken these medications within the last two weeks.

- you are taking antidepressants known as tricyclic antidepressants (TCAs) such as Tofranil® (imipramine), Anafranil® (clomipramine), Endep® (amitriptyline) or have taken these medications in the last two weeks.
- you are using or being given a sympathomimetic drug such as pseudoephedrine (found in cough and cold medications); adrenaline (epinephrine) e.g. EpiPen, noradrenaline (norepinephrine), dopamine and dobutamine.
- 8. you have a stomach ulcer
- 9. the expiry date on the pack has passed.

If you take this medicine after the date has passed it may have no effect at all, or worse, an entirely unexpected effect.

10. the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor if:

- you are allergic to any other medicines or other substances such as foods, dyes or preservatives.
- you have or have ever had any other health problems especially:
- stomach ulcers
- liver or kidney disease
- high blood pressure (hypertension)

- psychosis (a condition causing abnormal thoughts)
- heart problems (angina or abnormal rhythm).
 ELDEPRYL tablets could make these conditions worse.
- you are or plan to become pregnant or to breast feed. The effects of this medicine in pregnant and breastfeeding women are unknown.
- 4. you are taking any oral contraceptives.
- you are taking any medicine that has a narrow therapeutic index which requires careful monitoring, such as digoxin (used in heart failure) and anticoagulants (blood thinner) e.g. warfarin
- you are taking any medicine that inhibits monoamine oxidase (e.g., linezolid to treat bacterial infections)
- you are taking any other medications having a dopamine effect (e.g. Madopar®, Sinemet®) or tramadol (e.g. Tramal®) or buprenorphine.

If you have not told your doctor about any of the above, tell them before you start taking ELDEPRYL tablets.

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

ELDEPRYL tablets are available only on prescription and it is usually co-prescribed with other medicines used in treating Parkinson's disease (e.g. Madopar®, Sinemet®). After taking ELDEPRYL tablets for a short time, your doctor may decrease the amount of Madopar®or Sinemet®that you are taking.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Swallow the prescribed dose of this medicine with a large glass of water while standing upright.

Do not stop taking it without your doctor's advice, because your symptoms of Parkinson's disease may worsen.

If you forget to take it

If it is almost time to take your next dose, skip the dose that you have missed and take your next dose when you are meant to. Otherwise take it as soon as you remember, then go back to taking your tablets as usual.

Do not double a dose to make up for a dose that you have missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too many ELDEPRYL tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ELDEPRYL.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery. If you become pregnant while taking this medicine, tell your doctor.

Side effects

Check with your doctor or pharmacist as soon as possible if you have any problems while you are taking ELDEPRYL tablets, even if you think that the problems are not connected with the medicine or are not listed in this leaflet.

Like all medicines, ELDEPRYL tablets can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

The most common side effects of ELDEPRYL tablets tend to be due to its interaction with certain drugs such as Madopar®and Sinemet®. These are usually mild in nature and normally disappear when your doctor lowers your dose of Madopar®or Sinemet®after you have started taking ELDEPRYL tablets.

Tell your doctor if you notice any of the following and they worry you:

- body aches and pains
- constipation
- diarrhoea
- dizziness
- dry mouth
- headaches
- light headedness or feeling faint
- nausea, vomiting
- sleep disorders
- stomach pains
- sweating more than usual
- abnormal thinking.
- increased desire for sex
- compulsive behaviours such as gambling, shopping, eating, and repetitive purposeless activities.

Tell your doctor immediately, or go to the nearest casualty at your

local hospital if you notice any of the following:

- increase in unusual body movements
- mood/mental changes (e.g. agitation, confusion, depression, hallucinations)
- chest pains
- breathing problems.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed here

may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the bottle, they may not keep as well.

Keep ELDEPRYL tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store ELDEPRYL tablets or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets which are left over.

Product description

What ELDEPRYL tablets look like

ELDEPRYL tablets are a round white tablet with a break line on one side. It is available in bottles of 100 tablets.

Ingredients

Active ingredient:

5 mg selegiline hydrochloride per tablet.

Inactive ingredients:

- starch-maize
- microcrystalline cellulose
- mannitol
- povidone
- magnesium stearate.

ELDEPRYL tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Orion Pharma (Aus) Pty Limited Level 24, Tower 3 300 Barangaroo Avenue, Sydney, NSW 2000, Australia Telephone: 1800 861 913

Australian Registration Number: AUST R 47465.

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