

Selgene

contains the active ingredient selegiline hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Selgene.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Selgene against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Selgene is used for

Selgene is used to treat some of the symptoms of Parkinson's disease.

It can be used alone or taken in combination with levodopa (another medicine used for Parkinson's disease). When taken together with levodopa, Selgene can help reduce the need for high levodopa doses.

Parkinson's disease is a condition that mainly affects body movement. The three main symptoms of Parkinson's disease are:

- * shaking (tremor)
- * muscle stiffness
- * slow and unsteady movement.

These symptoms are caused by a lack of dopamine, a naturally occurring substance produced by certain brain cells.

Selgene belongs to a group of medicines called monoamine oxidase B inhibitors. It increases the amount of dopamine in the brain.

Ask your doctor if you have any questions about why Selgene has been prescribed for you.

Your doctor may have prescribed Selgene for another reason.

Selgene is available only with a doctor's prescription.

Selgene is not recommended for use in children, as its safety and effectiveness have not been established in this age group.

Before you take Selgene

When you must not take it

Do not take Selgene if you are allergic to medicines containing selegiline hydrochloride (e.g. Eldepryl) or any of the ingredients listed at the end of this leaflet.

Do not take Selgene if your doctor has already told you to stop taking levodopa.

Some medicines containing levodopa include Sinemet, Kinson and Madopar.

Do not take Selgene if you are taking, or have taken a selective serotonin reuptake inhibitor (SSRI) within the last 5 weeks.

Taking Selgene with a SSRI may cause severe side effects.

Ask your doctor or pharmacist if you are not sure whether you have been taking a SSRI.

SSRIs are medicines used for depression or anxiety disorders. Some examples of SSRIs include fluoxetine (Lovan, Prozac), paroxetine (Aropax, Paxtine), sertraline (Zoloft).

Do not take Selgene if you are being treated with pethidine, a strong pain killer normally given by injection.

Taking Selgene with pethidine may cause severe side effects.

Do not take Selgene if the expiry date (EXP.) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Selgene if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have any medical conditions, especially the following:

- * heart problems such as angina, irregular heart beat or rhythm
- * high blood pressure
- * stomach (peptic) ulcer

- * psychosis, a severe mental condition involving loss of contact with reality and abnormal thoughts.
- * liver or kidney disease.

Tell your doctor if you are pregnant or plan to become pregnant.

Selgene is not recommended in pregnant women as its safety has not been determined. Your doctor will discuss the risks and benefits of taking Selgene during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is not known whether Selgene passes into breast milk. Your doctor will discuss the risks and benefits of taking Selgene when breastfeeding.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Selgene, or may affect how well it works. These include:

- * selective serotonin reuptake inhibitors (SSRIs), medicines for depression and anxiety, e.g. fluoxetine (Lovan, Prozac), paroxetine (Aropax), sertraline (Zoloft)
- * monoamine oxidase inhibitors (MAOIs), medicines for depression, e.g. phenelzine (Nardil), tranylcypromine (Parnate)
- * tricyclic antidepressants, e.g. amitriptyline (Endep)
- * opioid pain killers such as morphine (MS Contin, Ordine), codeine
- * tramadol (Tramadol), another type of pain reliever
- * clozapine (Clozaril), a medicine used to treat schizophrenia

- * oral contraceptives (birth control pills).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Selgene.

How to take Selgene

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

Your doctor will tell you how much Selgene to take and when to take it. The maximum recommended dose of Selgene is 5 mg twice daily.

Selgene is usually prescribed with other medicines for Parkinson's disease. After taking Selgene for a short time, your doctor may decrease the dosage of the other medicines.

When to take Selgene

Take your medicine at about the same time each day (usually at breakfast and lunch).

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Selgene can be taken with or without food.

How to take Selgene

Swallow the tablets with a glass of water.

How long to take Selgene for

Keep taking Selgene for as long as your doctor recommends.

Selgene helps control the symptoms of Parkinson's disease, but does not cure it.

If you forget to take Selgene

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much Selgene (overdose)

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

You may need urgent medical attention.

If you take too much Selgene, you may feel sweaty, faint, lightheaded or dizzy, or have chest pains.

While you are taking Selgene

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Selgene.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Selgene.

If you become pregnant while taking Selgene, tell your doctor.

Since Selgene is meant to be taken regularly every day, keep a continuous supply of medicine so you don't run out, especially over weekends or on holidays.

Things you must not do

Do not use Selgene to treat any other conditions unless your doctor tells you to.

Do not give Selgene to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Selgene affects you.

Selgene may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Selgene.

Selgene helps most people with Parkinson's disease, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- * dizziness, lightheadedness, feeling faint
- * tiredness
- * headaches
- * dry mouth
- * feeling sick, vomiting, stomach pain, loss of appetite
- * hiccup, burping
- * constipation
- * trouble sleeping
- * sweating more than usual
- * abnormal vision
- * difficulty passing urine
- * swelling of the feet and legs.

The above list includes the milder side effects of Selgene.

Tell your doctor immediately if you notice any of the following:

- * an increase in unusual body movements, e.g. uncontrollable twitching, jerking or writhing movements
- * changes in mood such as depression or anxiety
- * hallucinations (seeing or hearing things that are not there), confusion
- * skin rash.

The above side effects are serious and may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * chest pain
- * fast or irregular heart beats, also called palpitations
- * shortness of breath, difficulty breathing.

The above side effects are very serious and require urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell while you are taking Selgene.

Other side effects not listed above may also occur in some patients. Some of these side effects (for example, changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

After taking Selgene

Taking other medicines

Do not take any of the following medicines within two weeks of stopping Selgene:

- * pethidine
- * tricyclic antidepressants
- * selective serotonin reuptake inhibitors.

Taking Selgene with any of these medicines may cause severe side effects.

Storage

Keep Selgene where children cannot reach it.

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

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

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

Do not leave Selgene in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Selgene is a round, white tablet marked SN/5 and G.

Each bottle contains 100 tablets.

Ingredients

The active ingredient in Selgene is selegiline hydrochloride. Each tablet contains 5 mg of selegiline hydrochloride.

The tablets also contain the following inactive ingredients:

- * lactose
- * maize starch
- * citric acid monohydrate
- * povidone
- * purified talc
- * magnesium stearate.

The tablets are gluten free.

Manufacturer

Selgene is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

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