

# PARKINSON INFORMATION

 Parkinson Society Canada  
Soci t  Parkinson Canada

## Pr **STALEVO\*** (levodopa, carbidopa and entacapone)

**This info sheet is based on *Stalevo\* Product Monograph, Part III: Consumer Information*<sup>1</sup>. It is a summary and does not tell you everything about the drug. Contact your doctor or pharmacist for more information.**

### **What is this medication?**

Stalevo\* was approved by Health Canada in February 2008. It is used to treat people with Parkinson's when the effect of each levodopa dose becomes shorter and the person subsequently experiences fluctuations in Parkinson's symptoms (commonly known as "end-of-dose wearing-off"<sup>2</sup>).

### **What's in the drug?**

Stalevo\* contains three active substances in one tablet. Each tablet contains levodopa (used to treat Parkinson's symptoms), and two other substances: carbidopa and entacapone (to help improve the effects of levodopa).

### **How does the drug work?**

Symptoms of Parkinson's are related to a decrease in the amount of dopamine in certain areas of the brain. Levodopa is given to increase the levels of dopamine in the brain. Part of the dose of levodopa is broken down in the body to an inactive substance, before it reaches the brain. Entacapone and carbidopa help to prevent this breakdown so that enough levodopa gets to the brain, where it will be converted to dopamine.

Stalevo\* is prescribed to help relieve the symptoms of Parkinson's, such as shaking of the limbs, stiffness and slowness of movement.

### **What dosage does it come in?**

The drug is available in three dosage strengths: 50/12.5/200 mg, 100/25/200 mg and 150/37.5/200 mg tablets. Your doctor will tell you how many tablets to take each day. Always take this drug exactly as your doctor has instructed. Do not stop taking this drug unless your doctor tells you to.

### **What should I tell my health care provider before using this drug?**

Before you use this drug, talk to your doctor or pharmacist if:

- You have had a heart attack, asthma or any other diseases of the heart, blood vessels or lungs.
  - You have a liver problem.
  - You have a severe kidney problem.
  - You have had kidney, liver or hormone-related diseases.
  - You have had stomach ulcers.
  - You have had convulsions.
  - You have any form of severe mental disorder.
  - You feel depressed, have suicidal thoughts, or notice unusual changes in your behaviour.
  - You are taking other medicines that can cause low blood pressure. You should be aware that this drug may make these reactions worse.
- You have chronic wide-angle glaucoma. Your dose may need to be adjusted and the pressure in your eyes may need to be monitored.
- Uncontrolled movements begin or get worse after you start taking this drug. Your doctor may need to change the dose of your Parkinson medications.
  - You have been told by your doctor that you have a hereditary intolerance to some sugars
  - You are taking any iron supplements or multi-vitamins containing iron.

### **What are the side effects of this medication?**

Entacapone enhances the effects of levodopa. If you were not previously taking entacapone tablets with your levodopa/carbidopa tablets, switching to this medication may cause an increase in certain side effects of levodopa, such as uncontrolled movements, feeling sick (i.e., nausea), being sick (i.e., vomiting) or hallucinations.

You should talk to your doctor if your muscles get very rigid or jerk violently, or if you suffer from tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. Also talk to your doctor if you experience diarrhea, as a follow-up of weight is recommended in order to prevent excessive weight loss.

The following side effects were reported by some people who used this drug in research studies. If you experience these side effects, talk to your doctor as soon as possible. They may be relieved by adjusting the dose.

**Most common side effects:**

- Uncontrolled movements.
- Feeling sick (nausea); loss of appetite; vomiting; abdominal pain; dry mouth; constipation; diarrhea, weight loss.
- Mental changes, including paranoid and psychotic symptoms, feeling agitated, depression (possibly with thoughts of suicide), problems with memory or thinking, hallucinations, and confusion.
- Itching and rash.
- Reddish-brown discolouration of the urine.

**Less common side effects:**

- Irregular heart beat; chest pain; shortness of breath.
- Light-headedness or fainting due to low blood pressure; dizziness; drowsiness.
- Sudden worsening of Parkinson's symptoms.
- Bleeding in the stomach; ulcers.
- High blood pressure; inflammation of the veins in the legs.
- Sleeplessness; unpleasant dreams, including nightmares; tiredness.
- Muscle cramps; increased sweating; more frequent falling.
- Tiredness (which may be due to changes in blood cells), fainting, infections; bleeding; tingling or numbness; convulsions.

**NOTE:** The above is not a complete list of side effects. For any unexpected effects while taking this drug, contact your doctor or pharmacist.

**Warnings and precautions when using this drug:**

Some people feel sleepy, drowsy, or, rarely, may suddenly fall asleep without warning (i.e. without feeling sleepy or drowsy) when taking this drug. Take special care when you drive or operate a machine. If you experience excessive drowsiness or a sudden sleep onset episode, do not drive or operate machines and contact your doctor immediately.

**Are there other considerations I need to know?**

If using this drug, you should be aware of the following:

*Risk of melanoma.* Studies of people with Parkinson's show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's. This problem may be associated with Parkinson's or the drugs used to treat it. Therefore, your doctor should perform periodic skin examinations, if you are taking this drug.

*Surgery and anaesthesia.* If you are going to have surgery with a general anaesthesia, inform the doctor that you are taking this drug.

*Driving and using machines.* This drug may lower your blood pressure, which may make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you operate any tools or machines (see warnings box).

*Older people.* If you are over 65, you can take this drug without dose adjustment. Speak to your doctor.

*Pregnant and breast-feeding women.* If you are pregnant or think you may be pregnant, do not take this drug before talking with your doctor. If you are breast-feeding, tell your doctor. You should not breastfeed while taking this drug.

*Interactions with other medications.* Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any to lower your blood pressure, antidepressants, non-prescription medicines (i.e., supplements or vitamins), or herbal products.

### **Who manufactures this drug?**

The drug is manufactured by Novartis Pharmaceuticals Canada Inc.

### **Further information:**

Health Canada collects information on serious and unexpected side effects of drugs. To report serious or unexpected side effects, notify Canada Vigilance, 1-866-234-2345 or [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca).

<sup>1</sup>Full document of Product Monograph available at Health Canada web site:  
<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>.

<sup>2</sup> The phenomenon, called “wearing off”, occurs when the dose of levodopa that initially controlled Parkinson’s symptoms is no longer enough to maintain full control until the next dose.

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