

Package leaflet: Information for the user
Stalevo 75 mg/18.75 mg/200 mg film-coated tablets
Levodopa/carbidopa/entacapone

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

1. What Stalevo is and what it is used for

Stalevo contains three active substances (levodopa, carbidopa and entacapone) in one film-coated tablet. Stalevo is used for the treatment of Parkinson's disease.

Parkinson's disease is caused by low levels of a substance called dopamine in the brain. Levodopa increases the amount of dopamine and hence reduces the symptoms of Parkinson's disease. Carbidopa and entacapone improve the antiparkinson effects of levodopa.

2. What you need to know before you take Stalevo

Do not take Stalevo if you:

- are allergic to levodopa, carbidopa or entacapone, or any of the other ingredients of this medicine (listed in section 6)
- have narrow-angle glaucoma (an eye disorder)
- have a tumour of the adrenal gland
- are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO-inhibitors)
- have ever had neuroleptic malignant syndrome (NMS – this is a rare reaction to medicines used to treat severe mental disorders)
- have ever had non-traumatic rhabdomyolysis (a rare muscle disorder)
- have a severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Stalevo if you have or have ever had:

- a heart attack or any other diseases of the heart including cardiac arrhythmias, or of the blood vessels
- asthma or any other disease of the lungs

- a liver problem, because your dose may need to be adjusted
- kidney or hormone-related diseases
- stomach ulcers or convulsions
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon
- any form of severe mental disorder like psychosis
- chronic wide-angle glaucoma, because your dose may need to be adjusted and the pressure in your eyes may need to be monitored.

Consult your doctor if you are currently taking:

- antipsychotics (medicines used to treat psychosis)
- a medicine which may cause low blood pressure when rising from a chair or bed. You should be aware that Stalevo may make these reactions worse.

Consult your doctor if during the treatment with Stalevo you:

- notice that your muscles get very rigid or jerk violently, or if you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. If any of this happens, **contact your doctor immediately**
- feel depressed, have suicidal thoughts, or notice unusual changes in your behaviour
- find yourself suddenly falling asleep, or if you feel very drowsy. If this happens, you should not drive or use any tools or machines (see also section 'Driving and using machines')
- notice that uncontrolled movements begin or get worse after you started to take Stalevo. If this happens, your doctor may need to change the dose of your antiparkinson medicine
- experience diarrhoea: monitoring of your weight is recommended in order to avoid potentially excessive weight loss
- experience progressive anorexia, asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time. If this happens, a general medical evaluation including liver function should be considered
- feel the need to stop using Stalevo, see section 'If you stop taking Stalevo'.

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of Stalevo and other medicines used to treat Parkinson's disease.

Tell your doctor if you or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or a preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Your doctor may take some regular laboratory tests during a long term treatment with Stalevo.

If you must undergo surgery, please tell your doctor that you are using Stalevo.

Stalevo is not recommended to be used for treatment of extrapyramidal symptoms (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions) caused by other medicines.

Children and adolescents

Experience with Stalevo in patients under 18 years is limited. Therefore, the use of Stalevo in children or adolescents is not recommended.

Other medicines and Stalevo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Stalevo if you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO inhibitors).

Stalevo may increase the effects and side effects of certain medicines. These include:

- medicines used to treat depression such as moclobemide, amitriptyline, desipramine, maprotiline, venlafaxine and paroxetine
- rimiterole and isoprenaline, used to treat respiratory diseases
- adrenaline, used for severe allergic reactions
- noradrenaline, dopamine and dobutamine, used to treat heart diseases and low blood pressure
- alpha-methyl dopa, used to treat high blood pressure
- apomorphine, which is used to treat Parkinson's disease.

The effects of Stalevo may be weakened by certain medicines. These include:

- dopamine antagonists used to treat mental disorders, nausea and vomiting
- phenytoin, used to prevent convulsions
- papaverine used to relax the muscles.

Stalevo may make it harder for you to digest iron. Therefore, do not take Stalevo and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

Stalevo with food and drink

Stalevo may be taken with or without food. For some patients, Stalevo may not be well absorbed if it is taken with, or shortly after eating protein-rich food (such as meats, fish, dairy products, seeds and nuts). Consult your doctor if you think this applies to you.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not breast-feed during treatment with Stalevo.

Driving and using machines

Stalevo may lower your blood pressure, which may make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you use any tools or machines.

If you feel very drowsy, or if you sometimes find yourself suddenly falling asleep, wait until you feel fully awake again before driving or doing anything else that requires you to be alert. Otherwise, you may put yourself and others at risk of serious injury or death.

Stalevo contains sucrose

Stalevo contains sucrose (1.4 mg/tablet). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Stalevo

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For adults and elderly:

- Your doctor will tell you exactly how many tablets of Stalevo to take each day.
- The tablets are not intended to be split or broken into smaller pieces.
- You should take only one tablet each time.
- Depending on how you respond to treatment, your doctor may suggest a higher or lower dose.
- If you are taking Stalevo 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg or 150 mg/37.5 mg/200 mg tablets, do not take more than 10 tablets per day.

Talk to your doctor or pharmacist if you think the effect of Stalevo is too strong or too weak, or if you experience possible side effects.

To open the bottle for the first time: open the closure, and then press with your thumb on the seal until it breaks. See picture 1.

Picture 1



If you take more Stalevo than you should

If you have accidentally taken more Stalevo tablets than you should, talk to your doctor or pharmacist immediately. In case of an overdose you may feel confused or agitated, your heart rate may be slower or faster than normal or the colour of your skin, tongue, eyes or urine may change.

If you forget to take Stalevo

Do not take a double dose to make up for a forgotten tablet.

If it is more than 1 hour until your next dose:

Take one tablet as soon as you remember, and the next tablet at the normal time.

If it is less than 1 hour until your next dose:

Take a tablet as soon as you remember, wait 1 hour, then take another tablet. After that carry on as normal.

Always leave at least an hour between Stalevo tablets, to avoid possible side effects.

If you stop taking Stalevo

Do not stop taking Stalevo unless your doctor tells you to. In such a case your doctor may need to adjust your other antiparkinson medicines, especially levodopa, to give sufficient control of your symptoms. If you suddenly stop taking Stalevo and other antiparkinsonian medicines it may result in unwanted side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Many of the side effects can be relieved by adjusting the dose.

If you during the treatment with Stalevo experience the following symptoms, **contact your doctor immediately**:

- Your muscles get very rigid or jerk violently, you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. These can be symptoms of neuroleptic malignant syndrome (NMS, a rare severe reaction to medicines used to treat disorders of the central nervous system) or rhabdomyolysis (a rare severe muscle disorder).
- Allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulties in breathing or swallowing.

Very common (may affect more than 1 in 10 people)

- uncontrolled movements (dyskinesias)
- feeling sick (nausea)
- harmless reddish-brown discolouration of urine
- muscle pain
- diarrhoea

Common (may affect up to 1 in 10 people)

- light-headedness or fainting due to low blood pressure, high blood pressure
- worsening of Parkinson's symptoms, dizziness, drowsiness
- vomiting, abdominal pain and discomfort, heartburn, dry mouth, constipation
- inability to sleep, hallucinations, confusion abnormal dreams (including nightmares), tiredness
- mental changes – including problems with memory, anxiety and depression (possibly with thoughts of suicide)
- heart or artery disease events (e.g. chest pain), irregular heart rate or rhythm
- more frequent falling
- shortness of breath
- increased sweating, rashes
- muscle cramps, swelling of legs
- blurred vision
- anaemia
- decreased appetite, decreased weight
- headache, joint pain
- urinary tract infection

Uncommon (may affect up to 1 in 100 people)

- heart attack
- bleeding in the gut
- changes in the blood cell count which may result in bleeding, abnormal liver function tests
- convulsions
- feeling agitated
- psychotic symptoms
- colitis (inflammation of the colon)
- discolourations other than urine (e.g. skin, nail, hair, sweat)
- swallowing difficulties
- inability to urinate

Not known (cannot be estimated from the available data)

Craving for large doses of Stalevo in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of Stalevo.

The following side effects have also been reported:

- hepatitis (inflammation of the liver)

- itching

You may experience the following side effects:

- Inability to resist the impulse to perform an action that could be harmful, which may include:
 - strong impulse to gamble excessively despite serious personal or family consequences
 - altered or increased sexual interest and behaviour of significant concern to you or to others for example, an increased sexual drive
 - uncontrollable excessive shopping or spending
 - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stalevo

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 bottle and the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Stalevo contains

- The active substances of Stalevo are levodopa, carbidopa and entacapone.
- Each Stalevo 75 mg/18.75 mg/200 mg tablet contains 75 mg of levodopa, 18.75 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are croscarmellose sodium, magnesium stearate, maize starch, mannitol (E421) and povidone (E1201)
- The ingredients in the film-coating are glycerol (85 per cent) (E422), hypromellose, magnesium stearate, polysorbate 80, red iron oxide (E172), sucrose, and titanium dioxide (E171).

What Stalevo looks like and contents of the pack

Stalevo 75 mg/18.75 mg/200 mg: light brownish red, oval film-coated tablets marked with 'LCE 75' on one side.

Stalevo 75 mg/18.75 mg/200 mg tablet comes in five different pack sizes (10, 30, 100, 130 or 175 tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.