

Stalevo[®]

levodopa/carbidopa/entacapone

Read all of this leaflet carefully before you start taking this medicine

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist.

This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

If any of the side effects affects you severely, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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Stalevo 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg, 150/37.5/200 mg, 200/50/200 mg film-coated tablets

The **active substances** of Stalevo are levodopa, carbidopa and entacapone.

The **other ingredients** are croscarmellose sodium, magnesium stearate, maize starch, mannitol, povidone, glycerol 85%, hypromellose, polysorbate 80, red iron oxide (E 172), sucrose, titanium dioxide (E 171), yellow iron oxide (E 172).

1 What Stalevo is and what it is used for

Stalevo contains three active substances in one film-coated tablet. Each tablet contains levodopa, used to treat Parkinson's disease. The two other active substances: carbidopa and entacapone improve the antiparkinson effects of levodopa.

Stalevo is available in six different dosage strengths: 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg, 150/37.5/200 mg and 200/50/200 mg film-coated tablets and comes in four different pack sizes (10, 30, 100, or 250 tablets).

Stalevo tablets have a thin brownish- to greyish-red coating over an orange to yellow core.

Stalevo 50/12.5/200 mg tablets: brownish- to greyish-red, round, convex tablets marked with 'LCE 50' on one side.

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

Stalevo 100/25/200 mg: brownish- to greyish-red, oval tablets marked with 'LCE 100' on one side.

Stalevo 125/31.25/200 mg: light brownish red, oval tablets marked with 'LCE 125' on one side.

Stalevo 150/37.5/200 mg: brownish- to greyish-red, elongated-ellipse shaped tablets marked with 'LCE 150' on one side.

Stalevo 200/50/200 mg: dark brownish red, oval-shaped tablets marked with 'LCE 200' on one side.

Your doctor has prescribed Stalevo to treat your Parkinson's disease.

Parkinson's disease is a disorder of the nervous system. It is caused by a lack of dopamine, a natural substance that is produced in the brain. Dopamine relays messages in the part of the brain that controls muscle movement. When too little dopamine is produced, problems with movement result.

Levodopa works by increasing the level of dopamine in the brain.

Stalevo helps in relieving the symptoms of Parkinson's disease, such as shaking of the limbs, and stiffness and slowness of movement, which make it difficult to perform normal daily activities.

You may also be given other medicines to help treat this condition.

Ask your doctor if you have any questions about how this medicine works or why this medicine has been prescribed for you.

2 Before you take Stalevo

Do not take Stalevo

- **If you are allergic** (hypersensitive) to levodopa, carbidopa or entacapone or any of the other ingredients of Stalevo.
- **If you have a severe liver impairment.**
- **If you have narrow-angle glaucoma** (an eye disorder).
- **If you have a tumour of the adrenal gland** (known as pheochromocytoma; this may increase the risk of severe high blood pressure).
- **If you are taking certain medicines to treat depression** (selective MAO-A plus MAO-B inhibitors, or non-selective MAO-inhibitors).
- **If you have ever had neuroleptic malignant syndrome** (NMS; this is a rare reaction to medicines used to treat severe mental disorders).
- **If you have ever had non-traumatic rhabdomyolysis** (a rare muscle disorder).

If any of these applies to you, talk to your doctor before taking Stalevo.

Take special care with Stalevo

- If you have ever had a heart attack, asthma or any other diseases of the heart, blood vessels or lungs.
- If you have a liver problem.
- If you have a severe renal problem.
- If you have ever had kidney, liver or hormone-related diseases.
- If you have ever had inflammatory bowel disease
- If you have ever had stomach ulcers.
- If you have ever had convulsions.
- If you have ever suffered from any form of severe mental disorder.
- If you feel depressed, have suicidal thoughts, or notice unusual changes in your behaviour.
- If you have chronic wide-angle glaucoma. Your dose may need to be adjusted and the pressure in your eyes may need to be monitored.
- If you are taking other medicines that can cause low blood pressure. You should be aware that Stalevo may make these reactions worse.
- If uncontrolled movements begin or get worse after you start taking Stalevo, your doctor may need to change the dose of your antiparkinson medications.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 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 (known as dopamine dysregulation syndrome).
- Tell your doctor if you or your family/caregiver 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.

If any of the above applies to you, **contact your doctor**.

- **If you find yourself suddenly falling asleep**, or if you feel very drowsy (see also the section 'Driving and using machines').
- **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** (signs of Neuroleptic Malignant Syndrome, NMS).
- **If you experience diarrhea**, your doctor may follow-up on your weight in order to prevent potential excessive weight loss.
- If you experience progressive anorexia, asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time, contact your doctor. He/she may decide to conduct a general medical evaluation including liver function.

If any of these occurs, tell your doctor immediately.

If you are going to have a surgery with a general anaesthesia, inform the doctor that you are taking Stalevo.

If you feel the need to stop using Stalevo, please consult your doctor first. It may be necessary to reduce the dose of Stalevo gradually, and make changes in your other antiparkinson medication, in order to prevent side effects and keep your Parkinson's symptoms from getting worse.

Older people

If you are over 65, you can take Stalevo without dose adjustment.

Children and adolescents

The use of Stalevo has not been established in children and adolescents less than 18 years of age and can therefore not be recommended.

Pregnant women

If you are pregnant or think you may be pregnant, do not take Stalevo before consulting your doctor. Stalevo is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risk of taking Stalevo during pregnancy.

Breast-feeding mothers

If you are breast-feeding, tell your doctor. You should not breast-feed while under 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 operate any tools or machines.

If you feel very drowsy, or if you sometimes find yourself suddenly falling asleep, you must not drive or do anything else that requires you to be alert (operate tools or machines). Consult your doctor for advice. Otherwise, you may put yourself and others at risk of serious injury or death.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any to lower your blood-pressure, non-prescription medicines or herbal products.

Stalevo may increase the effects and side effects of certain antidepressants and some other medicines. These include MAO-A inhibitors (e.g. moclobemide), tricyclic antidepressants (e.g. amitriptyline) and noradrenaline reuptake inhibitors (e.g. desipramine, maprotiline and venlafaxine), as well as paroxetine, rimiterole, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa and apomorphine.

Watch out for additional effects if you take these medicines while being treated with Stalevo.

The effects of Stalevo may be weakened by certain medicines. It includes medicines:

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

Tell your doctor if you are taking these medicines, or if you notice that Stalevo does not work as well when you take them.

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.

3 How to take Stalevo

Always take Stalevo exactly as your doctor has instructed you to. You should check with your doctor or pharmacist if you are unsure.

How much to take

Each Stalevo tablet contains one complete dose of levodopa, carbidopa and entacapone. Each time you take Stalevo, take only one tablet. The tablet is not intended to be split or broken into smaller pieces.

Your doctor will tell you exactly how many tablets of Stalevo to take each day. Depending on how you respond to treatment, your doctor may suggest a higher or lower dose.

Stalevo 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg and 150/37.5/200 mg: Do not take more than 10 tablets a day.

Stalevo 200/50/200 mg: Do not take more than 7 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 detect possible side effects.

When and how to take Stalevo

Strictly follow your doctor's instructions on when and how to use Stalevo, other levodopa medications and other antiparkinson drugs. Check with your doctor or pharmacist if you are unsure about these instructions or the text printed on the packaging.

Taking 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.

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.

If you forget to take Stalevo

If there is more than an hour until your next dose: take one tablet now, and the next tablet at the normal time.

If there is less than an hour until your next dose: take a tablet now, wait an hour, then take another tablet. After that go back to your normal schedule.

Do not take a double dose to make up for forgotten doses. Always leave at least an hour between Stalevo tablets, to avoid possible side effects.

If you are unsure about what to do, consult your doctor.

If you take more Stalevo than you should

If you have accidentally taken too many Stalevo tablets, **talk to your doctor immediately**. You may require medical attention.

Stopping Stalevo treatment

Do not stop taking Stalevo unless your doctor tells you to. In such case, your doctor may need to re-adjust the dosage of your other antiparkinson medications, especially levodopa, to give sufficient control of your symptoms. Abrupt discontinuation of both Stalevo and other antiparkinsonian medication may result in unwanted side effects, such as severe muscular stiffness, high fever and altered consciousness.

4 Possible side effects

Patients taking Stalevo can experience side effects. If you experience any of these side effects, talk to your doctor as soon as you can. Many of the side effects can be relieved by adjusting the dose.

If during the treatment with Stalevo you 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.

If you notice any other possible side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Very common (affecting more than 1 user in 10)

- Uncontrolled movements (dyskinesias);
- feeling sick (nausea);
- harmless reddish-brown discolouration of the urine;
- muscle pain;
- diarrhoea.

Common (affecting 1 to 10 users in 100)

- heart or artery disease events other than a heart attack (e.g. chest pain); irregular heart rate or rhythm;
- 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; mental changes, including problems with memory or thinking; anxiety and depression (possibly with thoughts of suicide); tiredness; chest pain;
- more frequent falling; impaired walking; loss of both strength and energy;
- shortness of breath;
- increased sweating; rashes;
- muscle cramps; involuntary muscle contractions; swelling of legs;
- blurred vision;
- anaemia; decreased appetite; decrease weight;
- headache; joint pain;
- urinary tract infection.

Uncommon (affecting 1 to 10 users in 1,000)

- Heart attack;
- bleeding in the gut;
- abnormal liver function tests; psychotic symptoms; feeling agitated;
- inflammation of the colon (colitis);
- Skin, nail, hair and sweat discolourations;
- changes in the blood cell count which may result in bleeding;
- swallowing difficulties;
- inability to urinate;
- generally feeling unwell.

Some side effects can be rare or very rare

- convulsions.

Other

The exact frequencies of these side effects are not known but are based upon reports received since the product has been on the market:

- hepatitis (inflammation of the liver);
- itching;
- excessive daytime somnolence; sudden sleep onset episodes;
- craving for large doses of Stalevo in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe uncontrolled movements (dyskinesias), mood swings, or other side effects after taking large doses of Stalevo;
- behavioural changes such as urge to gamble (pathological gambling) or increased sexual desire urges (increased libido and hypersexuality).

If any of the side effects get serious, tell your doctor, nurse or pharmacist.

5 Storing Stalevo

- Store below 30°C.
- Do not use after the expiry date printed on the pack.
- Do not use if the pack is damaged or shows signs of tampering.
- Keep out of the reach and sight of children.

6 Sponsor

Stalevo is supplied in New Zealand by:
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c/o Max Health Ltd
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