

STALEVO[®] FILM COATED TABLET

Levodopa/Carbidopa/Entacapone

(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)

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What Stalevo is used for

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

How Stalevo works

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.

Before you use Stalevo

When you must not use it:

- 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, or have taken in the last two weeks, medication for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- 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.

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.

Before you start to use it

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 or depression.
 - A type of glaucoma called wide angle glaucoma
 - You are due to have surgery
 - You have blood disorder
- If any of the above applies to you, contact your doctor.

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.

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.

Taking other medicines

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

interfere with each other. These include:

- other medicines for Parkinson's disease
- some medicines used to treat high blood pressure
- some medicines used to treat depression
- some medicines for psychiatric disorders
- some medicines for nausea and vomiting
- phenytoin, medicine for seizure
- papaverine, a medicine used to expand blood vessels to treat men with erectile dysfunction
- warfarin, a medicine used to prevent blood clots
- medicines containing iron, such as iron tablets

You may need to take different amounts of your medicines or to take different medicines while you are taking Stalevo. Your doctor and pharmacist have more information.

How to use 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 use

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 to use 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.

How long to use Stalevo

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.

If you forget to use Stalevo

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

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

While you are using it

Things you must do

- 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/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.

Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give Stalevo to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of***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.

Side effects

As with all medicines, patients treated with Stalevo may experience side effects, although not everybody gets them. 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;

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 or personal 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 behaviors; your doctor will discuss ways of managing or reducing the symptoms.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Stalevo***Storage***

- There are no special storage conditions.
- 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.
- Do not store above 30°C

- **Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

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.

Not all strength and pack sizes are marketed.

Ingredients:

- **Active ingredients**

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

- **Inactive ingredients**

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).

MAL Number:

Stalevo 50/12.5/200mg film-coated tablets:

MAL20051345ARZ

Stalevo 75/18.75/200 mg film-coated tablet:

MAL11030095ACRZ

Stalevo 100/25/200 mg film-coated tablet:

MAL20051339ARZ

Stalevo 125/31.25/200 mg film-coated tablet:

MAL11030094ACRZ

Stalevo 150/37.5/200 mg film-coated tablets:

MAL20051355ARZ

Stalevo 200/50/200 mg film-coated tablet:

MAL09102942ACRZ

Manufacturer

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Product Registration Holder

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