

STALEVO®

Levodopa/carbidopa anhydrous/entacapone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Stalevo.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from

www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Stalevo is used for

Stalevo is used to treat the symptoms of 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.

Stalevo contains three active ingredients: levodopa, carbidopa anhydrous and entacapone. Levodopa is a chemical closely related to dopamine, which allows the body to make its own dopamine. Levodopa works by increasing the level of dopamine in the brain. Carbidopa makes sure that enough levodopa gets to the brain where it is needed, and entacapone makes the effect of levodopa last longer.

Stalevo helps to relieve symptoms such as shaking of the limbs, stiffness and slowness of movement, which make it difficult to perform normal daily activities. Other medicines can also be added to help treat this condition.

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

Your doctor may have prescribed it for another purpose.

This medicine is only available with a doctor's prescription. It is not habit-forming.

There is not enough information to recommend this medicine for children under 18 years of age.

Before you take Stalevo

When you must not take it

Do not take Stalevo if you have ever had an allergy to any medicines containing levodopa, carbidopa or entacapone (the active ingredients in Stalevo) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Stalevo if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) such as phenelzine and tranlycypromine.

Taking Stalevo together with some, but not all, MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know whether or not the MAOI medicine you are taking can be safely taken with Stalevo.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Do not take Stalevo if you are pregnant.

There is not enough information to recommend its use during pregnancy.

Do not breast-feed while you are taking Stalevo.

It is not known if the active ingredient in Stalevo passes into

breast milk and could affect your baby.

Do not take Stalevo if you have any of the following health problems / medical conditions:

- a problem with your liver
- a tumour of the adrenal gland (called phaeochromocytoma), which could cause your blood pressure to rise to a dangerous level
- you have ever had a serious condition called neuroleptic malignant syndrome (NMS), with symptoms such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure
- you have ever had a condition called rhabdomyolysis, with symptoms of severe muscle weakness that was not due to an injury.
- unusual skin lumps or moles which have not been examined by your doctor, or if you have ever had skin cancer or melanoma.
- have a type of glaucoma called narrow-angle glaucoma.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Tell your doctor if you have an intolerance to sucrose.

This medicine contains sucrose.

Do not take Stalevo after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

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

Your doctor will discuss the possible risks and benefits of using Stalevo during pregnancy.

Tell your doctor if you have, or have ever had any medical

condition, especially the following:

- depression, mental disturbances, or you recognise anti-social behaviour
- heart disease, including irregular heart beat, also known as arrhythmia
- kidney problems
- lung problems including asthma
- hormonal problems
- convulsions or fits
- a type of glaucoma called wide-angle glaucoma
- stomach ulcers
- problems with your gall bladder
- inflammatory bowel disease

Your doctor may need to adjust the dose of Stalevo in some of these cases.

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Taking other medicines

Tell your doctor if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) such as phenelzine and tranylcypromine.

Taking Stalevo together with some, but not all, MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know whether or not the MAOI medicine you are taking can be safely taken with Stalevo.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these 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:

- some antibiotics such as erythromycin, rifampicin, ampicillin and chloramphenicol
- apomorphine, a medicine used in Parkinson's Disease
- adrenaline, a medicine used in some local anaesthetics and in emergency treatment of allergic reactions
- cholestyramine, a medicine used to reduce high levels of cholesterol in the blood
- papaverine, a medicine used to expand blood vessels to treat men with erectile dysfunction
- probenecid, a medicine used to prevent gout
- some medicines used to treat high blood pressure
- other medicines for Parkinson's disease
- some medicines for depression
- some medicines for psychiatric disorders
- methyldopa, a medicine for high blood pressure
- isoniazid, a medicine used to treat tuberculosis
- some medicines for nausea and vomiting
- phenytoin, a medicine used to treat convulsions
- medicines containing iron, such as iron tablets or multiple vitamins
- warfarin, a medicine used to prevent blood clots

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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Stalevo

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

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

People with moderate to severe Parkinson's disease usually take from 3 to 7 tablets of Stalevo each day.

For 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, the maximum dose is 10 tablets each day.

For Stalevo 200/50/200 mg: The maximum dose is 7 tablets each day.

Take only one STALEVO tablet at each dose.

Do not take 2 or more STALEVO tablets at a time.

Do not break the tablets into halves.

How to take it

Take the tablet with a full glass of water.

If your stomach is upset after taking the tablet, take it with a meal or after a snack.

It does not matter if you take Stalevo with or without food but avoid a high protein meal.

If you are taking any medicines containing iron, take them at least 2 or 3 hours before or after a dose of Stalevo.

If you take the two medicines at the same time, your body may absorb less iron than usual.

How long to take it

Do not stop taking this medicine without first checking with your doctor.

You may need to take Stalevo for a long time to control your symptoms. If you stop taking it, the dose of your other medicines for Parkinson's disease may have to be increased to prevent your symptoms from getting worse.

If you forget to take it

If it is almost time for your next dose (say, within an hour of the next dose), skip the dose you missed and take your next dose when you are meant to.

If you forget to take a tablet of Stalevo, you should take it as soon as you notice that you have forgotten to take your medication.

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

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Center (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Stalevo. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Stalevo

Things you must do

If you experience times where Stalevo does not appear to be working as well as it did previously, tell your doctor.

If you become pregnant, tell your doctor immediately.

You should not take this medicine while you are pregnant.

Before having any surgery or other hospital treatment, tell the anaesthetist or the doctor in charge that you are taking Stalevo.

It may cause unwanted side effects if you take it at the same time as some medicines that are used in hospital.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Stalevo.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Stalevo.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may also want to take some tests from time to time to help prevent unwanted side effects.

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.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not reduce the dose or stop treatment abruptly without consulting your doctor.

It may be necessary to reduce the dose of Stalevo gradually in order to prevent side effects.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Stalevo until you know how it affects you.

This medicine may increase the dizziness, light-headedness or sleepiness that sometimes happens when you take levodopa. Very rarely it can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

These symptoms may be a sign of low blood pressure. You can usually prevent them by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Be careful not to eat a diet high in protein.

The amount of levodopa absorbed by the body may be impaired if you eat a diet high in protein. Ask your doctor, pharmacist or dietician to check your diet.

Side effects

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

All medicines can have side effects. Sometimes they are serious, but

most of the time they are not. You may need medical treatment if you get some of the side effects.

Some of the side effects listed below are more common at the beginning of treatment and may disappear as treatment continues.

Do not be alarmed by these lists 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 side effects and they worry you:

- nausea (feeling sick) or vomiting
- indigestion
- diarrhoea
- pain in the stomach
- constipation
- dry mouth
- dizziness or light-headedness
- unsteadiness when walking, or a lack of coordination in your movements or speech
- spinning sensation (vertigo)
- tiredness or sleepiness
- shakiness
- aches and pains
- muscle cramps and pain or joint pain
- headache
- increased sweating
- difficulty sleeping or unusual dreams
- feeling depressed or agitated
- a reddish-brown colour to the urine (this is harmless)
- weight gain or loss (these are less common side effects)
- blurred vision
- seeing double
- strong urge to urinate that cannot be delayed, which is followed by a sharp pain or burning sensation in the urethra when the urine is released (urinary tract infection).

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

- rash, itching or hives on the skin
- unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements
- symptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure
- extreme sleepiness or sudden onset of sleep in the middle of daytime activities
- worsening of your symptoms of Parkinson's disease
- 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.
- 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).
 - medicine use or repetitive purposeless activities.

Tell your doctor if you experience any of these behaviours.

Your doctor will discuss ways of managing or reducing the symptoms.

- confusion or hallucinations (seeing, hearing or feeling things that are not there)
- difficulty breathing, congestion in the chest, chest pain
- signs of possible anaemia (low amount of iron in your blood) such as tiredness, headaches, shortness of breath when exercising, dizziness and looking pale
- signs of possible liver problems such as loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyes
- temporary paralysis or weakness of muscles
- gastrointestinal bleeding (coughing up blood or blood in the stools)
- diarrhoea, usually with blood and mucus, stomach pain, fever

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using Stalevo

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place.
- Do not store Stalevo or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on windowsills.

Keep this medicine 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.

Disposal

If your doctor tells you to stop taking Stalevo or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

There are six strengths of Stalevo available and they each look different from one another.

- Stalevo 50/12.5/200 are round-shaped tablets marked with 'LCE 50' on one side
- Stalevo 75/18.75/200 are oval-shaped tablets marked with 'LCE 75' on one side
- Stalevo 100/25/200 are oval-shaped tablets marked with 'LCE 100' on one side
- Stalevo 125/31.25/200 are oval-shaped tablets marked with 'LCE 125' on one side
- Stalevo 150/37.5/200 are ellipse-shaped tablets marked with 'LCE 150' on one side.
- Stalevo 200/50/200 are oval-shaped tablets marked with 'LCE 200' on one side.

Stalevo 50/12.5/200 mg, 100/25/200 mg and 150/37.5/200 mg are brownish- or greyish-red; 200/50/200 mg is a dark brownish-red; and 75/18.75/200 mg and 125/31.25/200 mg are light brownish red film-coated tablets

All six strengths of Stalevo are available in bottles of 30 tablets (sample pack) and 100 tablets (commercial pack).

Ingredients

Stalevo is supplied in 6 strengths:

- Stalevo 50/12.5/200 containing 12.5 mg carbidopa anhydrous, 50 mg levodopa, and 200 mg entacapone
- Stalevo 75/18.75/200 containing 18.75 mg carbidopa anhydrous,

75 mg levodopa, and 200 mg entacapone

- Stalevo 100/25/200 containing 25 mg carbidopa anhydrous, 100 mg levodopa, and 200 mg entacapone
- Stalevo 125/31.25/200 containing 31.25 mg carbidopa anhydrous, 125 mg levodopa, and 200 mg entacapone
- Stalevo 150/37.5/200 containing 37.5 mg carbidopa anhydrous, 150 mg levodopa, and 200 mg entacapone
- Stalevo 200/50/200 containing 50 mg carbidopa anhydrous, 200 mg levodopa, and 200 mg entacapone

Apart from the active ingredients, levodopa, carbidopa anhydrous and entacapone, Stalevo tablets contain the following inactive ingredients.

- croscarmellose sodium
- magnesium stearate
- starch - maize
- mannitol
- povidone
- glycerol
- hypromellose
- magnesium stearate
- polysorbate 80
- iron oxide red CI77491
- sucrose
- titanium dioxide
- iron oxide yellow CI77492.

Stalevo does not contain gluten, tartrazine or any other azo dyes.

Sponsor

Stalevo is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road,
Macquarie Park,
NSW 2113, AUSTRALIA
Tel: 1800 726 369

®= Registered Trademark

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Australian Registration Number.

Stalevo (50/12.5/200) tablet
AUST R 96372

Stalevo (75/18.75/200) tablet
AUST R 160686

Stalevo (100/25/200) tablet
AUST R 96395

Stalevo (125/31.25/200) tablet
AUST R 160687

Stalevo (150/37.5/200) tablet
AUST R 96396

Stalevo (200/50/200) tablet
AUST R 146890