

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

STALEVO® 50/12,5 Film-coated tablets

STALEVO® 100/25 Film-coated tablets

STALEVO® 150/37,5 Film-coated tablets

Read all of this leaflet carefully before taking STALEVO

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor or your pharmacist.**
- **STALEVO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

1. WHAT STALEVO CONTAINS

The active ingredients in **STALEVO** are levodopa, carbidopa and entacapone.

STALEVO 50/12,5 Film-coated tablets contain:

50 mg levodopa, 12,5 mg carbidopa and 200 mg entacapone.

STALEVO 100/25 Film-coated tablets contain:

100 mg levodopa, 25 mg carbidopa and 200 mg entacapone.

STALEVO 150/37,5 Film-coated tablets contain:

150 mg levodopa, 37,5 mg carbidopa and 200 mg entacapone.

The other ingredients are croscarmellose sodium, magnesium stearate, maize starch, mannitol, povidone K30.

The film-coating contains: glycerol 85%, hypromellose, magnesium stearate, polysorbate 80, red iron oxide (E172), sucrose, titanium dioxide (E171), yellow iron oxide (E172)

2. WHAT STALEVO 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 effects of levodopa in treating Parkinson's disease.

STALEVO is used to treat patients with Parkinson's disease who have end-of-dose motor fluctuations.

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

3. BEFORE YOU TAKE STALEVO

Do not take STALEVO:

- **If you are allergic** (hypersensitive) to levodopa, carbidopa or entacapone or any of the other ingredients in STALEVO.
- **If you are pregnant or breastfeeding.**
- **If you have a severe liver impairment.**
- **If you have narrow-angle glaucoma** (an eye disorder).
- **If you have suspicious undiagnosed skin lesions or history of melanoma** (darkening of skin as a result of a tumour)
- **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 or some antibiotics** (selective MAO-A plus MAO-B inhibitors, or non-selective MAO-inhibitors such as phenelzine, tranylcypromine and linezolid).

- **If you have ever had neuroleptic malignant syndrome (NMS;** this is a reaction to medicines used to treat severe mental disorders).
- **If you have ever had non-traumatic rhabdomyolysis** (a 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 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 STALEVO.
- Pathological gambling and increased sexual desire have been reported in Parkinson's disease patients treated with dopamine agonists and other dopaminergic medicines, including STALEVO.

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.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking STALEVO.

- You should not take STALEVO if you are pregnant.
- You should not breastfeed your baby if you are taking STALEVO.

Driving and using machinery:

- 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 with STALEVO:

Always tell your healthcare professional if you are taking any other medicine, including complementary medicines.

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.

4. HOW TO TAKE STALEVO

Do not share medicines prescribed for you with any other person.

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

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.

Do not take more than 10 tablets a day.

Your doctor will tell you how long your treatment with X will last. Do not stop taking treatment early because this may cause your symptoms to return. If you have the impression that the effect of STALEVO is too strong or too weak, tell your doctor or pharmacist.

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.
- If you experience diarrhoea, a follow-up of weight is recommended 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.

Older people

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

Children and adolescents

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

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 medicines. Check with your doctor or pharmacist if you are unsure about these instructions or the text printed on the packaging.

If you take more STALEVO than you should:

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

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.

Effects when treatment with STALEVO is stopped:

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.

5. POSSIBLE SIDE EFFECTS

STALEVO can have side effects. If you experience any of these side effects, talk to your doctor as soon as you can.

Not all side effects reported for STALEVO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking STALEVO, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking STALEVO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- muscles get very rigid or jerk violently,
- 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).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to STALEVO. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- hives (nettle rash),
- itching,
- rash,
- swelling of your face, lips tongue or throat.
- difficulties in breathing and swallowing.

These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

Frequent:

- uncontrolled movements (dyskinesias), worsening of Parkinson's symptoms
- feeling sick (nausea)
- harmless reddish-brown discolouration of urine
- light-headedness or fainting due to low blood pressure, high blood pressure
- heart or artery disease events other than a heart attack (e.g. chest pain), irregular heart rate or rhythm
- dizziness, drowsiness
- vomiting, abdominal pain and discomfort, heartburn, dry mouth, constipation, diarrhoea
- 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
- muscle cramps and pain; involuntary muscle contraction, swelling of legs
- blurred vision
- anaemia, decreased appetite, decrease weight
- headache, joint pain
- urinary tract infection

Less frequent:

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

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;

- behavioural changes such as urge to gamble (pathological gambling) or increased sexual desire urges (increased libido and hypersexuality).

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

6. STORAGE AND DISPOSAL OF STALEVO

Store at or below 25 °C.

Keep the container well-closed and store in a dry place protected from light.

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 all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

7. PRESENTATION OF STALEVO

100 tablets packed into white HDPE plastic containers with tamper evident PP plastic closures. Heat sealable aluminium foil innerseals.

8. IDENTIFICATION OF STALEVO

STALEVO® 50/12.5 Film-coated tablets:

Film-coated tablet, brownish- or greyish-red, round, biconvex tablets marked with "LCE 50" on one side. Diameter 11 mm.

NOVARTIS SA (PTY) LTD
STALEVO 50/12,5; 100/25 and 150/37,5 film-coated tablets
Levodopa/carbidopa/entacapone 50/12,5/200 mg; 100/25/200 mg and 150/37,5/200 mg per tablet
respectively
PIL Approved: 17 February 2017

STALEVO® 100/25 Film-coated tablets:

Film-coated tablet, brownish- or greyish-red, oval, tablets marked with "LCE 100" on one side.

Diameter 7,6 x 16,3 mm.

STALEVO® 150/37,5 Film-coated tablets:

Film-coated tablet, brownish- or greyish-red, elongated-ellipse shaped tablets marked with

"LCE 150" on one side. Diameter 9,3 x 14,31 mm.

9. REGISTRATION NUMBER

STALEVO® 50/12,5 Film-coated tablets: 38/5.4.1/0067

STALEVO® 100/25 Film-coated tablets: 38/5.4.1/0138

STALEVO® 150/37,5 Film-coated tablets: 38/5.4.1/0137

**10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
REGISTRATION**

NOVARTIS SOUTH AFRICA (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg, 2090

South Africa

11. DATE OF PUBLICATION

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