

Package leaflet: Information for the patient

Levodopa/Benserazide Orifarm 100 mg/25 mg tablets

levodopa/benserazide

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Levodopa/Benserazide Orifarm is and what it is used for

Levodopa/Benserazide Orifarm contains the active substances levodopa and benserazide and is used in the treatment of Parkinson's disease.

Dopamine is involved in nerve cell signaling within the body. Low dopamine levels in parts of the brain causes Parkinson's disease symptoms. Dopamine must, therefore, be given to counteract the prevailing deficiency. Since dopamine cannot reach the brain from other parts of the body, levodopa is given. This is converted into dopamine within the brain cells.

Benserazide is a substance that prevents levodopa from being converted to dopamine in other parts of the body, allowing the conversion to mainly take place in the brain. This is to avoid adverse effects on the other organs of the body.

Levodopa/Benserazide Orifarm helps to improve the signs of your Parkinson's disease; shaking, muscle stiffness, slow movements and difficulty in starting movements, difficulty swallowing, difficulty in keeping balance, abnormally large salivary secretion. Parkinson's disease is a lifelong disease and treatment must be continued throughout life.

2. What you need to know before you take Levodopa/Benserazide Orifarm

Do not take Levodopa/Benserazide Orifarm

- if you are allergic to levodopa or benserazide or any of the other ingredients of this medicine (listed in section 6).
- if you have hormonal disorders, such as adrenal marrow tumors, increased thyroid function and Cushing's syndrome.
- if you have a liver or kidney disease.
- if you have a heart disease, such as severe heart arrhythmia (heart rhythm disorders) and heart failure.
- if you have a psychiatric disorder with a psychotic component.

- if you have narrow angle glaucoma.
- if you are being treated with a combination of MAO-A and MAO-B inhibitors or non-selective MAO inhibitors (see “Other medicines and Levodopa/Benserazide Orifarm”).
- if you are younger than 25 years.
- if you are pregnant (see section “Pregnancy and breast-feeding”).
- if you are a fertile woman and do not use a safe method of contraception (see section “Pregnancy and breast-feeding”).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Levodopa/Benserazide Orifarm.

If you have a severe cardiovascular disease, increased pressure in the eye (glaucoma), have dementia or confusion, you should consult a doctor before starting treatment with Levodopa/Benserazide Orifarm.

During treatment your blood levels, your heart function and your kidney and liver function should be checked. If you have wide angle glaucoma, eye pressure should be measured regularly. If you have diabetes, your blood sugar levels should be checked regularly. Skin checks should also be done regularly during treatment with Levodopa/Benserazide Orifarm by e.g. a dermatologist.

Tell your doctor if you have previously had a rapid drop in blood pressure and experienced dizziness when getting up quickly.

Contact your doctor if you are experiencing increased sleepiness or have random sudden sleep attacks (see also section "Driving and using machines").

Patients with Parkinson's disease may be depressed and depression may also occur in patients treated with Levodopa/Benserazide Orifarm. Contact your doctor if you become depressed or experience mental changes during treatment with Levodopa/Benserazide Orifarm.

Tell your doctor if you or your family/carer notices that you develop a strong desire or lust to behave in ways that are unusual for you, or if you cannot resist the impulse, the urge or the temptation to perform certain activities that may harm you or others. These behaviors are called disturbed impulse control and may include gambling addiction, compulsive eating, compulsive buying, abnormally high sexual drive or an increase in sexual thoughts and feelings. Your doctor may need to reevaluate your treatment.

Use of Levodopa/Benserazide Orifarm can cause a syndrome called dopaminergic dysregulation syndrome leading to excessive use of the drug and in doses that are much higher than what have been prescribed by the doctor. This in turn can result in behavioral disorders. Contact your doctor if you experience this.

The treatment with Levodopa/Benserazide Orifarm must not be stopped suddenly, as you then, among other things, may have changes in blood pressure, fever, disturbances of consciousness and muscle stiffness which can be life threatening. Seek medical attention if a combination of these symptoms occurs.

Tell your doctor if you are going to have anesthesia during surgery.

Tell your doctor if you experience hypersensitivity reactions such as itching or rash.

Other medicines and Levodopa/Benserazide Orifarm

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

Levodopa/Benserazide Orifarm may be affected or it may affect other medicines, if taken at the same time. Therefore, talk to a doctor before using:

- trihexyphenidyl (an anticholinergic drug) that reduces the uptake rate of levodopa.
- iron sulphate, which reduces the uptake amount of levodopa.
- metoclopramide (used for nausea and vomiting), as it increases the uptake rate of levodopa.
- domperidone (a medicine for nausea, vomiting and acid regurgitation), may increase the uptake of levodopa from the gut into the body.

- certain medicines used for sedation and psychiatric disorders (e.g. medicines containing haloperidol, melperon, dixyrazine, chlorpromazine, levomepromazine, flufenazine, perfenazine, prochlorperazine, thioridazine).
- opioids (used for severe pain).
- certain medicines for high blood pressure (e.g. medicines containing reserpine), as dizziness when getting up quickly may occur.
- adrenaline or noradrenaline (used for asthma attacks, cardiac arrest, shock).
- amphetamine (used for ADHD).
- isoprenaline (used for stimulating the heart rate).
- methyl dopa (used for high blood pressure).
- amitriptyline or imipramine (used for depression).
- a combination of MAO-A (moclobemide) and MAO-B (selegiline, rasigiline) inhibitors or non-selective MAO inhibitors.
- other medicines for Parkinson's disease (anticholinergics, amantadine, COMT inhibitors or dopamine agonists), the dose of Levodopa/Benserazide Orifarm or the other medicines may need to be reduced.

Some laboratory analyzes may be affected by Levodopa/Benserazide Orifarm.

Levodopa/Benserazide Orifarm with food

The effect of Levodopa/Benserazide Orifarm can be reduced if taken with a protein-rich meal.

Pregnancy and breast-feeding

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.

Pregnancy

There is a potential risk that a fetus is affected by the medicine. Therefore, you must not use Levodopa/Benserazide Orifarm if you are pregnant, become pregnant or if you are a fertile woman and do not use a safe method of contraception.

- It is recommended to take a pregnancy test before starting treatment to rule out pregnancy.
- If you are able to get pregnant, you must use a safe contraceptive method.
- If you become pregnant, treatment must be stopped. Talk to a doctor concerning discontinuation (see “Warnings and precautions”) of your treatment.

Talk to your doctor before taking this medicine.

Breast-feeding

The active substances in the medicine pass into breast milk causing a risk for the child. Do not breast-feed while taking Levodopa/Benserazide Orifarm.

Driving and using machines

Levodopa/Benserazide Orifarm can have a major impact on the ability to drive and use machines. The medicine may cause increased sleepiness and random sudden sleep attacks. If you have any of these symptoms, you should not be driving or participating in activities as impaired attention may expose you, yourself or others for danger or risk of serious injury (e.g. when using machines).

Levodopa/Benserazide Orifarm contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Levodopa/Benserazide Orifarm

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

The dose is determined by the doctor, who will adjust it individually for you. **Never change the prescribed dose yourself without consulting your doctor. Do not stop treatment without consulting your doctor** (see “Warnings and precautions”).

Levodopa/Benserazide Orifarm should preferably be taken 30 minutes before or 1 hour after a meal. Nausea and other stomach discomfort can be relieved if you take the medicine together with a snack with a low protein content (e.g. a biscuit). Protein-rich foods may reduce the effect of the drug to some extent.

The tablets can be divided into equal doses.

Use in children, adolescents and young adults

The safety of Levodopa/Benserazide Orifarm in patients under 25 years of age has not been established. The medicine must therefore not be used by patients under 25 years.

If you take more Levodopa/Benserazide Orifarm than you should

If you have taken too much medicine or if e.g. a child accidentally has ingested the drug contact your doctor or go to the nearest hospital immediately.

Signs of overdose may include: disturbed heart rhythm, confusion, sleeping difficulties, feeling sick (e.g. nausea or vomiting) or sudden change in mobility.

If you forget to take Levodopa/Benserazide Orifarm

Do not take a double dose to make up for a forgotten tablet. If you forget a dose, wait until it is time for the next dose.

If you stop taking Levodopa/Benserazide Orifarm

Treatment with Levodopa/Benserazide Orifarm must not be stopped abruptly (see section “Warnings and precautions”).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people):

- Loss of appetite (anorexia)
- Stomach problems such as nausea, vomiting, diarrhea
- Disturbed heart rhythm
- Dizziness (when getting up quickly)
- Difficulty sleeping*
- Involuntary movements
- Rapid onset of variations in mobility (a condition known as “on and off” effects)
- Psychiatric disorders such as depression, confusion and hallucinations*.

Rare (may affect up to 1 in 1,000 people):

- Changes in the blood status (which are found through blood tests)
- Itching
- Rash
- A severe condition with altered blood pressure, altered consciousness, muscle stiffness and fever (similar to a condition called neuroleptic malignant syndrome) may in rare cases occur if treatment with Levodopa/Benserazide Orifarm is abruptly aborted.

Not known (frequency cannot be estimated from the available data):

- Agitation* (restless movement)
- Anxiety*

- Increased drowsiness and, in rare cases, random sudden attacks of sleep during the day
- Delusions*
- Disorientation*
- Discolored saliva, tongue, teeth or oral mucosa
- Decreased appetite
- Dopaminergic dysregulation syndrome (excessive use of the drug)
- After prolonged treatment, involuntary movements and fluctuations in the effect of the medication occur, which means that your mobility may suddenly change such as difficulties to move (legs are “freezing” when walking is initiated).
- Loss of or changed taste experience
- Hepatic or renal effects detected during sampling
- Restless leg syndrome
- Discolored urine.

* These side effects may especially occur in elderly patients and in patients who have or previously have had these diseases.

You may also experience the following side effects:

Not known (frequency cannot be estimated from the available data):

- Inability to resist an impulse to perform an act that may be harmful such as:
 - A strong impulse to excessive gambling despite serious consequences for you personally or for your family.
 - Changed or increased sexual interest or behavior that makes you or others noticeably concerned, e.g. an increased sexual drive.
 - Uncontrollable and excessive need to buy things and spend money.
 - Binge eating (eating large amounts of food in a short time) or compulsive eating (eating more food than normal and more than what is needed to satisfy your hunger).

Tell your doctor if you experience any of these behaviors to discuss ways to manage or reduce the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Levodopa/Benserazide Orifarm

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions.

Store in the original bottle and keep the bottle tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Levodopa/Benserazide Orifarm contains

- Active substances: 100 mg levodopa and 25 mg benserazide (as benserazide hydrochloride).
- Other ingredients: docusate sodium; iron oxide, red (E172); ethylcellulose (E462); silica, colloidal anhydrous; cellulose, microcrystalline (E460); starch, pregelatinized; mannitol (E421); calcium hydrogen phosphate, anhydrous (E341); crospovidone (E1202); magnesium stearate (E470b).

What Levodopa/Benserazide Orifarm looks like and contents of the pack

Round, pale red tablets with cross-score on both sides, 10 mm in diameter. The tablet can be divided into equal doses.

Pack sizes

Plastic bottle with child-resistant PE or PP cap containing a silica gel cannister. Pack sizes: 20, 30, 50, 60 or 100 tablets per bottle.

This silica gel cannister should not be discarded and must remain in the bottle, as the tablets are sensitive to moisture.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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