

Package leaflet: Information for the user

Carbidopa/Levodopa Orion 25 mg/100 mg tablets Carbidopa/Levodopa Orion 12.5 mg/50 mg tablets carbidopa/levodopa

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

What is in this leaflet

1. What Carbidopa/Levodopa Orion is and what it is used for
2. What you need to know before you take Carbidopa/Levodopa Orion
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1. What Carbidopa/Levodopa Orion is and what it is used for

Carbidopa/Levodopa Orion improves the signs of Parkinson's disease in adults. Parkinson's disease is a long-term illness where:

- you become slow and unsteady
- your muscles feel stiff
- you may develop shaking or trembling (called "tremor").

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities. Carbidopa/Levodopa Orion contains two different medicines called: levodopa and carbidopa.

- levodopa turns into a material called "dopamine" in your brain. The dopamine helps to improve the signs of your Parkinson's disease.
- carbidopa belongs to a group of medicines called "aromatic amino acid decarboxylase inhibitors". It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.

2. What you need to know before you take Carbidopa/Levodopa Orion

Do not take Carbidopa/Levodopa Orion

- if you are allergic to levodopa, carbidopa or any of the other ingredients of this medicine (listed in section 6)
- if you have suspicious skin lesions (moles) that have not been examined, or if you have had skin cancer
- if you are using so-called MAO inhibitors for the treatment of depression
- if you have narrow-angle glaucoma
- if you suffer from attacks of hypertension induced by tumor of the adrenal medulla (pheochromocytoma)
- hormonal problems (overproduction of cortisol or thyroid hormone)
- if you have severe heart disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbidopa/Levodopa Orion. It is important that before you start taking this medicine, tell your doctor about any medical problems you have or have had, especially if you have or have had

- heart attack or heart beat problems
- serious lung problems or asthmatic bronchitis
- kidney, liver or hormonal problems
- depression or mental problems
- ulcer
- a history of fits (convulsions)
- suspected skin lesions or a history of skin cancer (melanoma).

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of Carbidopa/Levodopa Orion and other medicines used to treat Parkinson's disease.

Tell your doctor if you or your family/carer 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 an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

This medication can affect some laboratory tests that your doctor may perform on blood or urine samples. Please remind your doctor if you are taking Carbidopa/Levodopa Orion and are having any tests.

Tell your doctor if you have previously used levodopa.

Children and adolescents

Carbidopa/Levodopa Orion is not recommended for patients aged under 18 years.

Other medicines and Carbidopa/Levodopa Orion

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

Treatment efficacy may change if Carbidopa/Levodopa Orion is used concomitantly with some other medicines. Tell your doctor if you are taking any of the following medicinal products:

- medicines for treatment of high blood pressure. The dose of these products may have to be adjusted.
- iron or iron products. Taking of Carbidopa/Levodopa Orion and iron preparations should be separated by the longest possible interval in time.
- anticholinergics and sympathomimetics
- certain medicines for the treatment of psychiatric conditions or antidepressants (such as phenothiazines, butyrophenones and risperidone)
- medicines for the treatment of tuberculosis (isoniazide)
- medicines for the treatment of muscle cramps, convulsions or other conditions causing involuntary movements (such as phenytoin)
- selegilin for the treatment of Parkinson's disease (excessive drop in blood pressure may occur in concomitant use)
- other medicines for Parkinson's disease such as tolcapone, entacapone or amantadine.

Carbidopa/Levodopa Orion with food

Try to avoid taking Carbidopa/Levodopa Orion with a meal containing proteins (such as, meat, eggs, milk, cheese) since the function of Carbidopa/Levodopa Orion may decrease.

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.

Carbidopa/Levodopa Orion is not recommended during pregnancy or in women of childbearing potential not using contraception unless the benefits for the mother outweigh the possible risk to the unborn baby.

Do not take Carbidopa/Levodopa Orion if you are breast-feeding.

Driving and using machines

Effects of the medicine may vary individually. Adverse effects that in some patients may influence the ability to drive or use machinery have been observed in connection with the use of carbidopa/levodopa (see "Possible side effects").

Carbidopa/Levodopa Orion may cause excessive somnolence and sudden, short-term sleep episodes. Therefore you should avoid driving a motor vehicle and situations (such as operating machinery) where impaired reaction ability might cause a risk of life-threatening injury, until repeated sleep episodes and somnolence have resolved.

Carbidopa/Levodopa Orion contains sodium

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

3. How to take Carbidopa/Levodopa Orion

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 usual daily dose may be variable and is individually determined by the doctor depending on the severity of the disease and the response to the treatment. During the dose adjustment period, the patient should pay special attention to symptoms such as involuntary movements, and inform your doctor immediately if this occurs. Your doctor will adjust your dosage as necessary.

More than one strength of Carbidopa/Levodopa Orion may be prescribed by your doctor. If you have been given different strengths of Carbidopa/Levodopa Orion, make sure that you are taking the correct tablet at the right time.

How to take this medicine

- Take this medicine by mouth by swallowing the tablet.
- Although your medicine can have an effect after one day, it may take up to seven days to work.
- Take the tablet at regular time intervals according to your doctor's instructions.
- Do not change the times at which you take your tablets or take any other medicines for Parkinson's disease without first consulting your doctor.
- Try to avoid taking your tablets with a protein-rich meal (see section 2 "Carbidopa/Levodopa Orion with food")

Carbidopa/Levodopa Orion 25 mg/100 mg: The tablet can be divided into equal doses.

Carbidopa/Levodopa Orion 12.5 mg/50 mg: The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Carbidopa/Levodopa Orion than you should

If you have taken more medicine than you should, or if a child has been taking medicine by accident, always contact your doctor or hospital to get an opinion of the risk and instructions on action to be taken.

If you forget to take Carbidopa/Levodopa Orion

Try to use Carbidopa/Levodopa Orion as instructed. However, if you forget to take a tablet, take it as soon as you remember. If the next medicine administration is almost due, do not take the forgotten tablet but continue with the usual schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Carbidopa/Levodopa Orion

Do not stop taking Carbidopa/Levodopa Orion or reduce the dosage without first discussing it with your doctor. Discontinuation of the medicine may cause some symptoms such as muscle stiffness, fever or mood alterations.

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

4. Possible side effects

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

Contact your doctor immediately if you have any of the following symptoms:

- hypersensitivity reactions, such as hives, itching, rash and swelling of the face, lips, tongue and/or throat that may cause breathing or swallowing problems
- chest pain
- irregular heart function
- dizziness when standing up quickly
- depression or psychotic symptoms, including delusions or hallucinations
- muscle stiffness, high body temperature, mental changes (these may be signs of neuroleptic syndrome)
- gastrointestinal bleeding
- convulsions
- blood disorders, the signs of which may include pale skin, fever, sore throat or mild bruising and prolonged bleeding after an injury.

Other side effects that may occur:

Very common (may affect more than 1 in 10 people):

- involuntary movements, such as twitching and convulsions.

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

- loss of appetite
- depression that may involve suicidal tendencies, confusion, abnormal dreams
- slowness of movement (the "on-off" phenomenon), dizziness, stinging and/or tingling or numbness of the skin, somnolence, sudden sleep episodes
- palpitations
- shortness of breath
- nausea, vomiting, diarrhoea.

Uncommon (may affect up to 1 in 100 people):

- agitation
- fainting
- hives
- muscle twitching.

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

- anemia
- dementia, convulsions have occurred in rare cases, but a causal relationship with carbidopa/levodopa treatment has not been established
- high blood pressure, vein inflammation
- duodenal ulcer, dark urine, sweat and/or saliva

- itching, vascular inflammation causing reddish rash and possibly abdominal and joint pain (Henoch Schönlein purpura), hair loss, rash.

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

- craving for large doses of carbidopa/levodopa in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of carbidopa/levodopa.

The following adverse effects associated with impulse control disorders may also occur:

Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:

- strong impulse to gamble excessively despite serious personal or 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 period of time) 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; they will discuss ways of managing or reducing the symptoms.

Other possible side effects:

- melanoma
- insomnia, anxiety, euphoria, disorientation, grinding your teeth
- impaired alertness, agitation, bitter taste in the mouth, weakness, headache, eyelid drooping and small pupils (activation of Horner's syndrome), muscle tone disorders, increased hand tremor, numbness
- diplopia, blurred vision, dilated pupils, staring upwards momentarily and inadvertently, eyelid cramps
- hot flushes, flushing
- hoarseness, changes in breathing rhythm, hiccups
- dry mouth, increased salivation, difficulty swallowing, abdominal pain and complaints, constipation, flatulence, heartburn or abdominal bloating, burning sensation of the tongue
- increased sweating
- muscle twitching, lockjaw (difficulty opening your mouth)
- difficulty urinating, urinary incontinence
- prolonged and painful erection
- weakness, general malaise, swelling, fatigue, walking difficulties
- weight gain or loss, falling.

Carbidopa/Levodopa Orion may influence some blood test results, such as elevate liver function test values and blood sugar values. Bacteria and blood have also been detected in the urine.

Carbidopa/Levodopa Orion may cause a false positive reaction for urinary ketone bodies.

If you have unusual symptoms, consult your doctor or seek treatment immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbidopa/Levodopa Orion

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

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and bottle label 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 Carbidopa/Levodopa Orion contains

- The active substances are carbidopa and levodopa. Each tablet contains carbidopa monohydrate equivalent to 12.5 mg or 25 mg carbidopa and 50 mg or 100 mg levodopa.
- The other ingredients are croscarmellose sodium, magnesium stearate, maize starch, mannitol (E421), povidone.

What Carbidopa/Levodopa Orion looks like and contents of the pack

Carbidopa/Levodopa Orion 25 mg/100 mg are white or off-white round tablets, 10 mm in diameter, scored and marked "LC 100" on one side.

Carbidopa/Levodopa Orion 12.5 mg/50 mg are white or off-white round tablets, 7 mm in diameter, scored and marked "LC 50" on one side.

Carbidopa/Levodopa Orion is available in a bottle containing 100 tablets.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic: Pipoda
Denmark, Finland, Ireland, Norway, Sweden: Carbidopa/Levodopa Orion
Hungary: Parlekarv
Poland: Parkador
Slovakia: Carlevo
Spain: Levodopa/Carbidopa Orion

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (Ireland) Limited, c/o Allphar Services Ltd, 4045 Kingswood Road, Citywest Business Park, Co Dublin.

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