

Package leaflet: Information for the user

Carbidopa/Levodopa Fair-Med 12.5 mg/50 mg tablets

Carbidopa/Levodopa Fair-Med 10 mg/100 mg tablets

Carbidopa/Levodopa Fair-Med 25 mg/100 mg tablets

Carbidopa/Levodopa Fair-Med 25 mg/250 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 Fair-Med is and what it is used for
2. What you need to know before you take Carbidopa/Levodopa Fair-Med
3. How to take Carbidopa/Levodopa Fair-Med
4. Possible side effects
5. How to store Carbidopa/Levodopa Fair-Med
6. Contents of the pack and other information

1. What Carbidopa/Levodopa Fair-Med is and what it is used for

Carbidopa/Levodopa Fair-Med improves the signs of Parkinson's disease. 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 Fair-Med 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 Fair-Med

Do not take Carbidopa/Levodopa Fair-Med:

- if you are allergic to carbidopa or levodopa or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor
- if you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors) used for depression. You need to stop using these medicines at least two weeks before you start Carbidopa/Levodopa Fair-Med (see also under 'Taking other medicines' below).

- if you have a condition called ‘narrow-angle glaucoma’ that may cause a sudden build up of pressure in the eye
- 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

Do not take Carbidopa/Levodopa Fair-Med if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking Carbidopa/Levodopa Fair-Med.

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbidopa/Levodopa Fair-Med:

- if you have a history of fits (convulsions)
- if you have a lung problem (such as bronchial asthma)
- if you have had an ulcer in your gut (called ‘duodenal’ or ‘peptic ulcer’) or have vomited blood
- if you have had a heart attack, heart beat problems, circulation problems
- if you are taking a medicine which may cause low blood pressure when rising from a chair or bed (orthostatic hypotension)
- if you have kidney or liver problems
- if you have hormonal problems
- if you have had depression or other mental problems
- if you have a condition called ‘chronic wide-angle glaucoma’ that may cause a build-up of pressure in the eye. You will need to have regular checks on the pressure in your eye.
- if you sometimes have sudden sleep attacks or sometimes feel very sleepy
- if you are due to have surgery.

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.

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 Fair-Med and other medicines used to treat Parkinson’s disease.

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 Fair-Med and are having any tests.

Other medicines and Carbidopa/Levodopa Fair-Med

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

This is because Carbidopa/Levodopa Fair-Med can affect the way some other medicines work. Also some other medicines can affect the way Carbidopa/Levodopa Fair-Med works.

In particular tell your doctor or pharmacist if you are taking other medicines for:

- Parkinson’s disease (such as tolcapone, entacapone, amantadine)
- Severe allergic reactions, asthma, chronic bronchitis, heart diseases and low blood pressure (such as anticholinergics and sympathomimetics)
- Fits (convulsions) or epilepsy (such as phenytoin)
- High blood pressure (antihypertensives)
- Mental problems (antipsychotics such as phenothiazines, butyrophenons and risperidone)
- Depression (such as ‘tricyclic antidepressants’ or ‘non-selective monoamine oxidase inhibitors’)
- Tuberculosis (such as isoniazide)
- Anxiety (such as benzodiazepines)
- Anaemia (such as iron tablets)
- Sickness (such as metoclopramide)

- Spasms in the blood vessels (such as papaverine).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Carbidopa/Levodopa Fair-Med with food and drink

Try to avoid taking your tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese) Carbidopa/Levodopa Fair-Med may not work as well as it should.

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.

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

Driving and using machines

Carbidopa/Levodopa Fair-Med may lower your blood pressure, which may make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you use any tools or machines. Carbidopa/Levodopa Fair-Med can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive or use tools or machines. Your doctor will tell you if you can start driving again if these attacks stop.

3. How to take Carbidopa/Levodopa Fair-Med

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 dosage will be decided by your doctor who will adjust the dosage individually for you.

Your doctor will monitor you on a regular basis and adjust your dosage if necessary.

Taking this medicine

- Take this medicine by mouth.
- Although your medicine can have an effect after one day, it may take up to seven days to work.
- Take them 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 heavy meal.

For doses not realisable/practicable with this medicinal product, other medicinal products are available.

If you have not had levodopa before

The usual starting dose is:

- for Carbidopa/Levodopa Fair-Med 12.5 mg/50 mg Tablets: one tablet three or four times a day.
- for Carbidopa/Levodopa Fair-Med 25 mg/100 mg Tablets: one tablet three times a day.
- for Carbidopa/Levodopa Fair-Med 10 mg/100 mg Tablets: one tablet three or four times a day.

If you have had levodopa before

- your doctor will ask you to stop taking your medicine for Parkinson's disease before you start taking Carbidopa/Levodopa Fair-Med.

More than one strengths of Carbidopa/Levodopa Fair-Med may be prescribed by your doctor.

If you have been given different strengths of Carbidopa/Levodopa Fair-Med tablets to take, make sure that you are taking the correct one at the right time.

Use in children and adolescents

Carbidopa/Levodopa Fair-Med is not recommended for children or adolescents under 18 years.

If you take more Carbidopa/Levodopa Fair-Med than you should

If you take too many tablets see your doctor immediately.

If you forget to take Carbidopa/Levodopa Fair-Med

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

If you stop taking Carbidopa/Levodopa Fair-Med

Do not stop taking Carbidopa/Levodopa Fair-Med or change your dose until your doctor tells you to. If you stop taking Carbidopa/Levodopa Fair-Med the following can occur: stiff muscles, high temperature (fever) and mental changes.

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.

Stop taking Carbidopa/Levodopa Fair-Med and see your doctor straight away, if you notice any of the following side effects:

- allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulty in breathing or swallowing
- chest pain
- uneven (irregular) heart beat or palpitations
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastro-intestinal bleeding)
- blood problems, the signs may include pale skin (pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury
- muscle stiffness, severe inability to sit still, high fever, sweating, increased salivation and impaired consciousness (neuroleptic malignant syndrome)
- mental changes including delusions, hallucinations and depression (very rarely) suicidal tendencies
- fits (convulsions).

Other side effects that may occur:

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

- Urinary tract infections

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

- loss of appetite (anorexia)
- confusion, dizziness, nightmares, drowsiness, tiredness, sleeplessness, feeling of well-being (euphoria), dementia, feeling of stimulation, dream abnormalities
- movement disorders (dyskinesia), a disorder characterised by sudden involuntary movements (chorea), muscle tone disorder (dystonia), movement disorders caused from outside the nervous system, sudden changes in Parkinson's symptoms ("on-off" symptoms), slowdown in movements during "on-off" periods (bradykinesia)
- a drop in blood pressure caused e.g. by getting up too quickly from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension), tendency to faint
- sudden loss of consciousness
- nausea, vomiting, dry mouth, bitter taste

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

- weight loss or weight gain

- disturbance of muscle coordination (ataxia), increase in hand tremors
- increase in blood pressure
- hoarseness, chest pain
- constipation, diarrhea, wind
- increased salivation, difficulties in swallowing
- fluid accumulation (oedema)
- muscle spasms
- dark urine
- loss of strength (asthenia), weakness
- feeling of being unwell (malaise)
- hot flushes

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

- a blood disorder (lack of white blood cells) accompanied by an increased susceptibility to infections (leukopenia), anaemia, a blood disorder (lack of blood platelets) accompanied by bruising and a tendency to bleed (thrombocytopenia)
- excitement (agitation), anxiety, impaired ability to think, disorientation, headache, increased sexual desire, numbness, fits/ seizures
- episodes of serious mental illness, during which control over one's own conduct and behaviour is impaired
- a serious condition as a result of using neuroleptics, which may manifest as muscle stiffness, a severe inability to sit still, high fever, sweating, increased salivation and impaired consciousness (neuroleptic malignant syndrome)
- feelings of prickling, tingling and itchiness without any apparent cause
- more frequent falling, gait disorders, lockjaw
- blurred vision, spasm of the orbicularis oculi muscle surrounding the eye (this may be a sign of overdose), activation of a pre-existing Horner's syndrome (an eye disorder), double vision, dilated pupils, a deterioration in eye movements
- inflammation of the veins
- breathlessness, abnormal breathing patterns
- impaired digestion with symptoms such as feelings of fullness in the upper abdomen, upper abdominal pain, belching, nausea, vomiting and heartburn (dyspepsia), stomach and intestinal pain, dark saliva, grinding of teeth, hiccups, stomach and intestinal bleeding, burning tongue, duodenal ulcers
- sudden build-up of fluid in the skin and mucous membranes (e.g. throat and tongue), breathing difficulties and/or itching and skin rash, often appearing as an allergic reaction (angioedema)
- skin rash with severe itching and the formation of wheals (urticaria), itching, facial redness, hair loss, skin rash, increased sweating, dark sweat
- in children, allergy-related bleeding in the skin and gastrointestinal tract wall (Schönlein- Henoch purpura)
- urine retention, involuntary passing of urine, persistent erection (priapism)

Very rare (may affect up to 1 in 10,000 people):

- a very serious blood disorder (lack of white blood cells) accompanied by sudden high fever, severe sore throat and mouth ulcers (agranulocytosis)
- drowsiness and constant daytime fatigue/ sudden attacks of sleep

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

- muscle twitching
- Craving for large doses of Carbidopa/Levodopa Fair-Med 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 Fair-Med.
- Inability to resist the impulse to perform an action that could be harmful, 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 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; they will discuss ways of managing or reducing the symptoms.

If any symptoms persist or you experience any other side effects please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 67625 1 7. Website: www.hpra.ie; E-mail: rnedsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbidopa/Levodopa Fair-Med

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

Do not use this medicine after the expiry date which is stated on the blister and carton 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 Fair-Med contains

- The active substances are carbidopa and levodopa.
Each tablet of Carbidopa/Levodopa Fair-Med contains 13.5 mg carbidopa monohydrate (equivalent to 12.5 mg of anhydrous carbidopa) and 50 mg levodopa.
Each tablet of Carbidopa/Levodopa Fair-Med contains 10.8 mg carbidopa monohydrate (equivalent to 10 mg of anhydrous carbidopa) and 100 mg levodopa.
Each tablet of Carbidopa/Levodopa Fair-Med contains 27.0 mg carbidopa monohydrate (equivalent to 25 mg of anhydrous carbidopa) and 100 mg levodopa.
Each tablet of Carbidopa/Levodopa Fair-Med contains 27.0 mg carbidopa monohydrate (equivalent to 25 mg of anhydrous carbidopa) and 250 mg levodopa.

- The other excipients are:

10 mg/100 mg and 25 mg/250 mg: crospovidone, indigo carmine lake (E132), magnesium stearate, cellulose microcrystalline, pregelatinised starch
12.5mg/50 mg and 25 mg/100 mg: crospovidone, quinoline yellow lake (E104), magnesium stearate, cellulose microcrystalline, pregelatinised starch

What Carbidopa/Levodopa Fair-Med looks like and contents of the pack

Carbidopa/Levodopa Fair-Med 12.5 mg/50 mg tablets are light yellow colored, round shaped, with a diameter of 6 mm, with “C” on one side and “17” on other side of tablet.

Carbidopa/Levodopa Fair-Med 10 mg/100 mg tablets are light blue colored, round shaped, with a diameter of 8 mm, with “C” on one side and “18” on other side of tablet.
Carbidopa/Levodopa Fair-Med 25 mg/100 mg tablets are light yellow colored, round shaped, with a diameter of 8 mm, with “C” on one side and “19” on other side of tablet.
Carbidopa/Levodopa Fair-Med 25 mg/250 mg tablets are light blue colored, round shaped, with a diameter of 10.40 mm, with “C” on one side and “20” on other side of tablet.

Pack-sizes:

12.5 mg/50 mg: blister packs of 30, 50, 90, 100 tablets
10 mg /100mg: blister packs of 30, 50, 90, 100 tablets
25 mg /100mg: blister packs of 20, 30, 50, 60, 90, 100, 120, 180, 200 tablets
25 mg /250mg: blister packs of 20, 30, 50, 60, 90, 100, 200 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Fairmed Healthcare GmbH
Dorotheenstraße 48
22301 Hamburg
Germany
pv@fair-med.com

Manufacturer:

Fairmed Healthcare GmbH
Maria-Goeppert-Straße 3
23562 Lübeck
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Carbidopa/Levodopa Fair-Med 12,5mg/50mg, 25mg/100mg
Sweden (RMS): Carbidopa/Levodopa - 12,5mg/50mg, 10mg/100mg, 25mg/100mg, 25mg/250mg tabletter
Germany: Levodopa/Carbidopa Fair-Med Healthcare 100mg/25mg, 250mg/25mg Tabletten
Ireland: Carbidopa/Levodopa Fair-Med 12.5mg/50mg, 10mg/100mg, 25mg/100mg, 25mg/250mg Tablets
Netherlands: Carbidopa/Levodopa Fair-Med, 12,5mg/50mg, 10mg/100mg, 25mg/100mg, 25mg/250mg tabletten
Norway: Carbidopa/Levodopa Fair-Med 12,5mg/50mg, 25mg/ 100mg
Portugal: Levodopa + Carbidopa Pharmakern 100mg/25mg, 250mg/25mg blister

This leaflet was last revised in .