

Summary Public Assessment Report

Carbidopa/Levodopa Fair-Med (carbidopa, levodopa)

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(carbidopa, levodopa)

Tablets, 12,5 mg/50 mg, 10 mg/100 mg, 25 mg/ 100 mg, 25 mg/250 mg

This is a summary of the public assessment report (PAR) for Carbidopa/Levodopa Fair-Med. It explains how Carbidopa/Levodopa Fair-Med was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Carbidopa/Levodopa Fair-Med.

For practical information about using Carbidopa/Levodopa Fair-Med, patients should read the package leaflet or contact their doctor or pharmacist.

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

Carbidopa/Levodopa Fair-Med is a 'generic medicine'. This means that Carbidopa/Levodopa Fair-Med is similar to a 'reference medicine' already authorised in the European Union (EU) called Sinemet.

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.

How does Carbidopa/Levodopa Fair-Med work?

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.

How is Carbidopa/Levodopa Fair-Med used?

The pharmaceutical form of Carbidopa/Levodopa Fair-Med is tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Carbidopa/Levodopa Fair-Med have been shown in studies?

Because Carbidopa/Levodopa Fair-Med is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Sinemet. Two

medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Carbidopa/Levodopa Fair-Med?

Because Carbidopa/Levodopa Fair-Med is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Carbidopa/Levodopa Fair-Med approved?

It was concluded that, in accordance with EU requirements, Carbidopa/Levodopa Fair-Med has been shown to have comparable quality and to be bioequivalent to the reference medicine Sinemet. Therefore, the Medical Products Agency in Sweden decided that, as for Sinemet, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Carbidopa/Levodopa Fair-Med?

A risk management plan has been developed to ensure that Carbidopa/Levodopa Fair-Med is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Carbidopa/Levodopa Fair-Med, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Carbidopa/Levodopa Fair-Med

The marketing authorisation for Carbidopa/Levodopa Fair-Med was granted on 2016-02-18 in Sweden.

The full PAR for Carbidopa/Levodopa Fair-Med can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Carbidopa/Levodopa Fair-Med, please read the [[package leaflet](#)] or contact your doctor or pharmacist.

This summary was last updated in 2016-03.