

Summary Public Assessment Report

Levodopa/Benserazide Owlpharma (levodopa, benserazide hydrochloride)

SE/H/2111/01/DC

Summary Public Assessment Report

Levodopa/Benserazide Owlpharma
levodopa, benserazide hydrochloride

Tablet, 100 mg/25 mg

This is a summary of the public assessment report (PAR) for Levodopa/Benserazide Owlpharma. It explains how Levodopa/Benserazide Owlpharma 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 Levodopa/Benserazide Owlpharma.

For practical information about using Levodopa/Benserazide Owlpharma, patients should read the package leaflet or contact their doctor or pharmacist.

What is Levodopa/Benserazide Owlpharma and what is it used for?

Levodopa/Benserazide Owlpharma is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Madopark.

Levodopa/Benserazide Owlpharma is used in the treatment of Parkinson's disease.

How does Levodopa/Benserazide Owlpharma work?

Levodopa/Benserazide Owlpharma contains the active substances levodopa and benserazide.

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.

These substances together increase the dopamine levels in the brain and helps to improve the signs of Parkinson's disease; shaking, muscle stiffness, slow movements and difficulty in starting movements, difficulty swallowing, difficulty in keeping balance, abnormally large salivary secretion.

How is Levodopa/Benserazide Owlpharma used?

The pharmaceutical form of Levodopa/Benserazide Owlpharma is tablet 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 in Sweden.

What benefits of Levodopa/Benserazide Owlpharma have been shown in studies?

Because Levodopa/Benserazide Owlpharma is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Madopark.

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

What are the possible side effects from Levodopa/Benserazide Owlpharma?

Because Levodopa/Benserazide Owlpharma is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Levodopa/Benserazide Owlpharma approved?

It was concluded that, in accordance with EU requirements, Levodopa/Benserazide Owlpharma has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Madopark. Therefore, the Swedish Medical Products Agency decided that, as for Madopark, 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 Levodopa/Benserazide Owlpharma?

A risk management plan has been developed to ensure that Levodopa/Benserazide Owlpharma 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 Levodopa/Benserazide Owlpharma, 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 Levodopa/Benserazide Owlpharma

The full PAR for Levodopa/Benserazide Owlpharma can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Levodopa/Benserazide Owlpharma

This summary was last updated in 2022-01.