LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lecigon
(entacapone, carbidopa (monohydrate), levodopa)

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Intestinal gel, 20 mg/ml + 5 mg/ml + 20 mg/ml

This is a summary of the public assessment report (PAR) for Lecigon. It explains how Lecigon 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 Lecigon.

For practical information about using Lecigon, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lecigon and what is it used for?

Lecigon is used for the treatment of Parkinson's disease. It is used in advanced cases where oral medicines (medicines taken by mouth) no longer provide a satisfactory result.

How does Lecigon work?

In a person with Parkinson's disease, the levels of dopamine in the brain are low. Dopamine itself does not cross the body´s own protective “blood-brain barrier” and is therefore not prescribed to a patient. Levodopa, instead, is converted into dopamine in the brain and relieves the symptoms of Parkinson's disease.

Carbidopa and entacapone improve the effect that levodopa has on Parkinson's disease. Levodopa is metabolised to release dopamine to a large extent also in other bodily tissues than the brain. By reducing the metabolism of levodopa in other parts of the body, carbidopa makes more levodopa available specifically to the brain. Addition of carbidopa also reduces the need for a higher dose of levodopa, resulting in less frequent side effects such as nausea. Entacapone prolongs the effect of levodopa by keeping the its blood levels steady longer by reducing its clearance from the body by the kidneys.

How is Lecigon used?

The pharmaceutical form of Lecigon is intestinal gel for continuous intestinal delivery with a certified pump.

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 Lecigon have been shown in studies?

Data from several studies and clinical experience predicted Lecigon to be effective in the treatment of advanced Parkinsons´s disease when oral combination of the substances have not given satisfactory results.

What are the possible side effects of Lecigon?

For the full list of all side effects reported with Lecigon, see section 4 of the package leaflet.

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

Why is Lecigon approved?

Based on the results from data described above the Medical Products Agency in Sweden was of the opinion that Lecigon's benefits are greater than its risks in patients with advanced disease where oral medicines no longer provide a satisfactory result and recommended Lecigon to be approved for use.

What measures are being taken to ensure the safe and effective use of Lecigon?

A risk management plan has been developed to ensure that Lecigon 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 Lecigon, 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 Lecigon

The full PAR for Lecigon can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lecigon, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-11.