LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Produodopa
(foslevodopa, foscarbidopa)

SE/H/415/03/DC

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Solution for infusion, 240 mg/ml + 12 mg/ml

This is a summary of the public assessment report (PAR) for Produodopa. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Produodopa and what is it used for?

Produodopa contains two active substances, foslevodopa and foscarbidopa, and is used to treat Parkinson's disease.

How does Produodopa work?

- In the body, foslevodopa is made into 'dopamine'. This adds to the dopamine already in your brain and spinal cord. Dopamine helps transfer signals between nerve cells.
- Too little dopamine causes Parkinson's disease signs like tremor, feeling stiff, slow movement, and problems keeping your balance.
- Treatment with foslevodopa increases the amount of dopamine in your body. This means it reduces these signs.
- Foscarbidopa improves the effect of foslevodopa. It also reduces the side effects of foslevodopa.

How is Produodopa used?

The pharmaceutical form is solution for infusion.

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 Produodopa have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating Parkinson's disease.

What are the possible side effects from Produodopa?

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 Produodopa approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Produodopa?”

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

A risk management plan has been developed to ensure that the product 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, 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.

Additional risk minimisation measures (including educational material)
The educational material consists of a patient educational material in the form of a guide to address the important identified risks of *infusion site events (infusion site infections and serious infusion site reactions).* The following key elements are addressed:

Section 1: Awareness (why the patient guide was developed and why patients/care givers should read it).

- This section reminds patients/care givers of the indication of ABBV-951, how it is administered and about the 2 risks of concern that are infusion site infections and infusion site reactions.

Sections 2 to 5: Education: In these sections, the patients and caregivers are educated on

- How patients should choose their infusion site
- How to recognize infusion site infection or reaction
- What patients can do to reduce the chance of getting infusion site infection or reaction
- What patients can do if they have infusion site infection or reaction to avoid a worst outcome
- Where patients can find more information about ABBV-951 (including how to report side effects)

Other information about Produodopa

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

This summary was last updated in 2023-01.