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EPAR summary for the public

Numient

levodopa / carbidopa

This is a summary of the European public assessment report (EPAR) for Numient. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Numient.

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

What is Numient and what is it used for?

Numient is used in adults to treat the symptoms of Parkinson's disease, a progressive brain disorder that causes shaking and muscular stiffness and slows down movement.

It contains the active substances levodopa and carbidopa.

How is Numient used?

Numient is available as capsules to be taken by mouth. The starting dose for patients who have not previously taken levodopa is one capsule containing 95 mg of levodopa and 23.75 mg of carbidopa, three times daily for the first three days. The doctor may then increase the dose depending on how the condition responds to treatment. For patients already taking levodopa, the doctor will determine the dose of Numient based on their current treatment.

Numient capsules are taken with a glass of water. They can be taken with or without food, but should not be taken at the same time as high protein meals, which can reduce absorption.

Patients who have difficulty swallowing can have the content of the capsules sprinkled on soft food such as apple sauce, yoghurt or pudding. The patient should then swallow the food immediately without chewing.

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Numient can only be obtained with a prescription and it is available in the following strengths: 95 mg/23.75 mg, 145 mg/36.25 mg, 195 mg/48.75 mg and 245 mg/61.25 mg. For further information on how to use Numient, see the summary of product characteristic (also part of the EPAR).

How does Numient work?

In patients with Parkinson's disease, the cells in the brain that produce dopamine, a neurotransmitter important for controlling movement, begin to die and the amount of dopamine in the brain decreases.

Numient contains levodopa which converts into dopamine in the brain and helps to restore dopamine levels. The carbidopa in Numient stops the levodopa from converting into dopamine while still in the general circulation, before it has reached the brain.

The combination of levodopa and carbidopa is used in other medicines for Parkinson's disease. In Numient, a portion of the active substances is released immediately, while the remaining is released gradually, leading to more steady levodopa levels. These types of capsules are known as modified-release capsules.

What benefits of Numient have been shown in studies?

In a study of 381 patients with early stage Parkinson's disease, Numient at various doses was more effective at improving symptoms than placebo (a dummy treatment). After 30 weeks, patients taking Numient had their symptoms improve by an average of between 11.7 and 14.9 points (depending on dose) on a standard symptom scale (Unified Parkinson's Disease Rating Scale, UPDRS Part II and Part III). Patients who took placebo had an average improvement of 0.6 points.

A second study compared Numient with another treatment containing levodopa and carbidopa in 393 patients with advanced Parkinson's disease. This study looked at how well the treatments reduced the time when patients have more difficulty moving about, called 'off periods'. After 13 weeks, patients taking Numient had off periods of about 24% of their waking hours compared with 30% of waking hours in patients taking the comparator medicine. Both groups had off periods of about 36-37% at the start of the study.

What are the risks associated with Numient?

The most frequent side effects with Numient are nausea in (12% of patients), dizziness, headache and involuntary movements (each occurring in 8% of patients), and insomnia (in 6% of patients). More serious side effects include bleeding from the gut and allergic reactions, and have been reported uncommonly.

Numient must not be used in patients with narrow angle glaucoma (an eye disorder) or pheochromocytoma (a tumour of the adrenal glands). It must also not be used in patients taking medicines known as non-selective monoamine oxidase (MAO) inhibitors or in patients with a history of certain medical conditions. For the full list of all side effects and restrictions, see the package leaflet.

Why is Numient approved?

Studies show that Numient is effective at reducing symptoms in patients with early and late stage Parkinson's disease. Another benefit is the way the active substances are formulated in Numient, which helps maintain more steady levodopa levels.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Numient's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Numient 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 Numient, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Numient

The European Commission granted a marketing authorisation valid throughout the European Union for Numient on 19 November 2015.

The full EPAR and risk management plan summary for Numient can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Numient, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.