LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sastravi
(levodopa/carbidopa/entacapone)

SE/H/1386/01-07/DC

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Sastravi

(levodopa/carbidopa/entacapone)

Film-coated tablet
50 mg/12.5 mg/200 mg
75 mg/18.75 mg/200mg
100 mg/25 mg/200mg
125 mg/31.25 mg/200mg
150 mg/37.5 mg/200mg
175 mg/43.75 mg/200 mg
200 mg/50 mg/200mg

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

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

What is Sastravi and what is it used for?

Sastravi is a 'generic medicine'. This means that Sastravi is similar to a 'reference medicine' already authorised in the European Union (EU) called Stalevo.

Sastravi is used for the treatment of Parkinson's disease.

How does Sastravi work?

Parkinson's disease is caused by low levels of a substance called dopamine in the brain. Levodopa increases the amount of dopamine and hence reduces the symptoms of Parkinson's disease. Carbidopa and entacapone improve the antiparkinson effects of levodopa.

How is Sastravi used?

The pharmaceutical form of Sastravi is film-coated 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 Sastravi have been shown in studies?

Because Sastravi is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Stalevo. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Sastravi?

Because Sastravi 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 Sastravi approved?

It was concluded that, in accordance with EU requirements, Sastravi has been shown to have comparable quality and to be bioequivalent to the reference medicine Stalevo. Therefore, the Medical Products Agency in Sweden decided that, as for Stalevo, 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 Sastravi?

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

The marketing authorisation for Sastravi was granted on 2014-08-28 in Sweden.

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

This summary was last updated in 2014-08-28.