LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tapidola
(levodopa/carbidopa/entacapone)

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Summary Public Assessment Report

Tapidola

(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
200 mg/50 mg/200mg

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

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

What is Tapidola and what is it used for?

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

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

How does Tapidola 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 Tapidola used?

The pharmaceutical form of Tapidola 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 Tapidola have been shown in studies?

Because Tapidola 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 Tapidola?

Because Tapidola 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 Tapidola approved?

It was concluded that, in accordance with EU requirements, Tapidola 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 Tapidola?

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

The marketing authorisation for Tapidola was granted on 2015-03-19 in Sweden.

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

This summary was last updated in 2015-03-19.