EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2019
EMA/CHMP/225317/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Striascan

ioflupane (^{123}I)

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Striascan, intended for the diagnosis of Parkinson's disease and other related diseases and dementia.

The applicant for this medicinal product is CIS BIO International.

Striascan will be available as a solution for injection (74 MBq/ml). The active substance of Striascan is ioflupane (^{123}I), a diagnostic radiopharmaceutical (ATC code: V09AB03) acting as a dopamine transporter imaging agent for single photon emission computed tomography (SPECT).

Striascan is a generic of DaTSCAN, which has been authorised in the EU since 27 July 2000. Studies have demonstrated the satisfactory quality of Striascan. Since Striascan is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product DaTSCAN was not required. A question and answer document on generic medicines can be found here.

The full indication is:

"This medicinal product is for diagnostic use only.

Striascan is indicated for detecting loss of functional dopaminergic neuron terminals in the striatum:

- In adult patients with clinically uncertain parkinsonian syndromes, for example those with early symptoms, in order to help differentiate essential tremor from parkinsonian syndromes related to idiopathic Parkinson's disease, multiple system atrophy and progressive supranuclear palsy. Striascan is unable to discriminate between Parkinson's disease, multiple system atrophy and progressive supranuclear palsy.
- In adult patients, to help differentiate probable dementia with Lewy bodies from Alzheimer's disease. Striascan is unable to discriminate between dementia with Lewy bodies and Parkinson's disease dementia."

Detailed recommendations for the use of this product will be described in the summary of product

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.