22 April 2021
EMA/CHMP/218686/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Celsunax

ioflupane (123I)

On 22 April 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Celsunax, intended for detecting loss of functional dopaminergic neuron terminals in the striatum.

The applicant for this medicinal product is Pinax Pharma GmbH.

Celsunax will be available as a solution for injection (74 MBq/ml). The active substance of Celsunax is ioflupane (123I), a diagnostic radiopharmaceutical product (ATC code: V09AB03). Ioflupane binds with to the presynaptic dopamine transporter, so radiolabelled ioflupane can be used as a surrogate marker to examine the integrity of the dopaminergic nigrostriatal neurons.

Celsunax is a generic of DaTSCAN, which has been authorised in the EU since 27 July2000. Studies have demonstrated the satisfactory quality of Celsunax. Since Celsunax 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.
>
> Celsunax 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. Celsunax 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. Celsunax is unable to discriminate between dementia with Lewy bodies and

[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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Parkinson’s disease dementia.

Celsunax should only be used in adult patients referred by physicians experienced in the management of movement disorders and/or dementia. Celsunax should only be used by qualified personnel with the appropriate government authorisation for the use and manipulation of radionuclides within a designated clinical setting.

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