

Summary of risk management plan for Celsunax (ioflupane (^{123}I))

This is a summary of the risk management plan (RMP) for Celsunax. The RMP details important risks of Celsunax, how these risks can be minimised, and how more information will be obtained about Celsunax' risks and uncertainties (missing information).

Celsunax' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Celsunax should be used.

This summary of the RMP for Celsunax should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Celsunax' RMP.

I. The medicine and what it is used for

Celsunax is authorised for diagnostic use only.

It 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 (ET) from Parkinsonian Syndromes (PS) related to idiopathic Parkinson's disease, Multiple System Atrophy and Progressive Supranuclear Palsy. Ioflupane (^{123}I) 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. Ioflupane (^{123}I) is unable to discriminate between dementia with Lewy bodies and Parkinson's disease dementia. (see SmPC for the full indication).

It contains ioflupane (^{123}I) as the active substance and it is given by intravenous injection.

Further information about the evaluation of Celsunax' benefits can be found in Celsunax' EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: <https://www.ema.europa.eu/en/medicines/human/EPAR/celsunax>.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Celsunax, together with measures to minimise such risks and the proposed studies for learning more about Celsunax' risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Celsunax are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Celsunax. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	-
Important potential risks	-
Missing information	-

II.B Summary of important risks

There are no important risks identified for Celsunax. The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Celsunax.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Celsunax.