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Celsunax *(ioflupane (^{123}I))*

An overview of Celsunax and why it is authorised in the EU

What is Celsunax and what is it used for?

Celsunax is a diagnostic medicine. It is used to detect the loss of nerve cells in an area of the brain called the striatum, specifically the cells that release dopamine, a chemical messenger.

The medicine is used to help in the diagnosis of the following conditions in adults:

- movement disorders such as those in Parkinson's disease and other related diseases, where a loss of nerve cells leads to tremor (shaking), gait disturbance (problems with the way the patient walks) and stiffness of the muscles. Because tremor can also occur in 'essential tremor' (tremor whose cause is unknown), Celsunax can help distinguish between essential tremor and diseases related to Parkinson's disease;
- dementia (loss of intellectual function). Celsunax is used to help distinguish between a type of dementia known as 'dementia with Lewy bodies' and Alzheimer's disease.

Celsunax contains the active substance ioflupane (^{123}I) and is a 'generic medicine'. This means that Celsunax contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called DaTSCAN. For more information on generic medicines, see the question-and-answer document here.

How is Celsunax used?

Celsunax can only be obtained with a prescription and should only be used in patients who have been referred by a doctor with experience in the management of movement disorders or dementia. Celsunax is only handled and given by people who have experience in the safe handling of radioactive materials.

Celsunax is given by slow injection lasting at least 15 to 20 seconds into an arm vein. A scan is taken 3 to 6 hours after the injection. Between 1 to 4 hours before receiving Celsunax, patients must also take another medicine, such as iodine tablets, to prevent the radioactive iodine in Celsunax from getting into the thyroid gland.

Resuscitation equipment should be available before Celsunax is given, in case the patient has an allergic reaction.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

For more information about using Celsunax, see the package leaflet or contact your doctor or pharmacist.

How does Celsunax work?

The active substance in Celsunax, ioflupane (^{123}I), is a radiopharmaceutical. It contains a substance called ioflupane, which is labelled with ^{123}I (iodine-123), a radioactive form of iodine. When Celsunax is injected, ioflupane (^{123}I) is distributed by the blood and builds up in the striatum. Here it attaches to structures on nerve cell endings that transport dopamine. This build-up can be seen using an imaging technique called single-photon-emission computed tomography (SPECT), which detects the radioactive iodine-123.

In patients with Parkinson's disease and related diseases, and in patients with dementia with Lewy bodies, there is typically a loss of the dopamine-containing nerve cells in the striatum. If this happens, the amount of Celsunax attaching to these nerve cells is greatly reduced, which can be seen on the scan. This enables diseases related to Parkinson's disease to be distinguished from essential tremor, and for Lewy body dementia to be distinguished from Alzheimer's disease.

How has Celsunax been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, DaTSCAN, and do not need to be repeated for Celsunax.

As for every medicine, the company provided studies on the quality of Celsunax. There was no need for 'bioequivalence' studies to investigate whether Celsunax is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Celsunax is given by injection into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Celsunax?

Because Celsunax is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Celsunax authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Celsunax has been shown to be comparable to DaTSCAN. Therefore, the Agency's view was that, as for DaTSCAN, the benefits of Celsunax outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Celsunax?

Recommendations and precautions to be followed by healthcare professionals for the safe and effective use of Celsunax have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Celsunax are continuously monitored. Side effects reported with Celsunax are carefully evaluated and any necessary action taken to protect patients.

Other information about Celsunax

Celsunax received a marketing authorisation valid throughout the EU on 17 June 2021.

Further information on Celsunax can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/celsunax. Information on the reference medicine can also be found on the Agency's website.

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