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EPAR summary for the public

DaTSCAN

ioflupane (^{123}I)

This document is a summary of the European public assessment report (EPAR) for DaTSCAN. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for DaTSCAN.

What is DaTSCAN?

DaTSCAN is a solution for injection that contains the active substance ioflupane (^{123}I).

What is DaTSCAN used for?

DaTSCAN is for diagnostic use only. 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 (aged 18 years or over):

- movement disorders such as those seen 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), DaTSCAN is used to help distinguish between essential tremor and diseases related to Parkinson's disease;
- dementia (loss of intellectual function). DaTSCAN is used to help distinguish between a type of dementia known as 'dementia with Lewy bodies' and Alzheimer's disease.

The medicine can only be obtained with a prescription.

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How is DaTSCAN used?

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

DaTSCAN is given by slow injection lasting no less than 15 to 20 seconds into an arm vein. A scan is taken three to six hours after the injection. When receiving DaTSCAN, patients must also take another medicine, such as iodine tablets, to prevent their thyroid gland from taking up the iodine contained in DaTSCAN. This is taken one to four hours before DaTSCAN.

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

How does DaTSCAN work?

The active substance in DaTSCAN, ioflupane (^{123}I), is a radiopharmaceutical. It contains a substance called ioflupane, which is labelled with ^{123}I (iodine-123), a radioactive form of the chemical element iodine. Ioflupane attaches specifically to structures on the surface of nerve cell endings in the striatum that are responsible for the transport of dopamine.

When DaTSCAN is injected, ioflupane (^{123}I) is distributed through the body in the blood and accumulates in the striatum, where it attaches to the structures that transport dopamine. This can be seen using a special 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 nerve cells in the striatum containing dopamine. If this happens, the amount of DaTSCAN 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 DaTSCAN been studied?

In movement disorders, DaTSCAN has been studied in 254 adults in two main studies. In the studies, images obtained in 45 healthy volunteers were compared with those obtained in 180 patients with Parkinson's disease or related diseases, and in 29 patients with essential tremor.

In dementia, DaTSCAN has been studied in one main study involving 288 adults who had been diagnosed with dementia with Lewy bodies or Alzheimer's disease, or another form of dementia.

In all of the studies, the main measure of effectiveness was the accuracy of the diagnosis based on the images from the scan compared with the diagnosis made by a specialist doctor.

What benefit has DaTSCAN shown during the studies?

In movement disorders, DaTSCAN was effective at detecting changes in the brain due to Parkinson's disease or related diseases. In the larger of the two studies, the sensitivity of DaTSCAN was 97%. This means that the disease identified by the doctor reading the images obtained using DaTSCAN matched the existing diagnosis of the patients in 97% of cases.

In dementia, the sensitivity of DaTSCAN in distinguishing dementia caused by Lewy bodies from other types of dementia ranged from 75 to 80%.

What is the risk associated with DaTSCAN?

No serious side effects have been reported with DaTSCAN. The most common side effect with DaTSCAN (seen in between 1 and 10 patients in 100) is headache. The risk caused by radioactivity is thought to be very low. For the full list of all side effects reported with DaTSCAN, see the package leaflet.

DaTSCAN should not be used in people who may be hypersensitive (allergic) to ioflupane or any of the other ingredients. It must not be used in women who are pregnant.

Why has DaTSCAN been approved?

The CHMP decided that DaTSCAN's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about DaTSCAN:

The European Commission granted a marketing authorisation valid throughout the European Union for DaTSCAN to GE Healthcare Limited on 27 July 2000. The marketing authorisation is valid for an unlimited period.

The full EPAR for DaTSCAN can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with DaTSCAN, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2011.