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Tauvid (*flortaucipir (^{18}F)*)

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

What is Tauvid and what is it used for?

Tauvid is a diagnostic medicine that is used during brain scans in adults with cognitive impairment (memory and thinking problems) who are being evaluated for Alzheimer's disease.

Tauvid is used during a type of scan called positron-emission tomography (PET) to help doctors assess the presence and distribution in the brain of abnormal forms of the tau protein, which are present in the brain of people with Alzheimer's disease.

Tauvid contains the active substance flortaucipir (^{18}F).

How is Tauvid used?

Tauvid can only be obtained with a prescription and PET scans with Tauvid should be requested by doctors experienced in the management of patients with diseases such as Alzheimer's and other dementias. The medicine should only be used in designated nuclear medicine facilities (where radioactive substances are used for the diagnosis and treatment of disease).

Tauvid is given by injection into a vein about 80 minutes before obtaining an image from a PET scan. This image should be read by a doctor specially trained in interpreting PET scans with Tauvid.

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

How does Tauvid work?

The active substance in Tauvid, flortaucipir (^{18}F), is a type of medicine known as a radiopharmaceutical that emits low amounts of radiation and works by targeting and attaching to abnormal forms of the tau protein. After it attaches to the protein, the radiation it emits can be detected by the PET scanner, enabling doctors to see the localisation of abnormal tau protein in the brain.

Tauvid PET scan results on their own are not sufficient to confirm or reject a diagnosis of Alzheimer's disease in patients with cognitive impairment. Doctors will therefore need to use the scans together with clinical evaluation and other diagnostic tools.

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What benefits of Tauvid have been shown in studies?

Tauvid was investigated in one main study involving 64 people nearing the end of their lives who had consented to autopsies after they died. Some of them had dementia, others had no memory or other cognitive problems.

The study participants underwent PET scan of the brain with Tauvid shortly before their death, and each scan was interpreted as positive (i.e. suggestive of Alzheimer's disease) or negative by five specialists; the patients' brain was then examined after their death. The study looked at sensitivity (the ability to detect the disease in patients with abnormal tau protein in the brain) and specificity (the ability to correctly identify absence of the disease) of the PET scans.

The results of the scans were compared with the results of the autopsies; PET scans performed with Tauvid were able to accurately identify the presence of abnormal tau protein aggregates in patients' brain, on average, in 92% of cases (sensitivity). Absence of abnormal tau protein was accurately identified, on average, in 76% of cases (specificity).

What are the risks associated with Tauvid?

For the full list of side effects and restrictions with Tauvid, see the package leaflet.

The most common side effects with Tauvid (which may affect up to 1 in 100 people) include headache, pain at the injection site and increase in blood pressure.

Why is Tauvid authorised in the EU?

At the time of Tauvid's authorisation, there was no other imaging tool for detecting the presence and distribution of abnormal tau protein aggregates in the brain of patients with cognitive impairment being evaluated for Alzheimer's disease.

Results from the main study showed that PET scans with Tauvid have a good sensitivity, and the lower specificity is considered acceptable since Tauvid is not used on its own, but together with other tools for the diagnosis of Alzheimer's disease. With regard to the safety of Tauvid, side effects were mild and considered acceptable.

The European Medicines Agency therefore decided that Tauvid's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Tauvid

Tauvid received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Tauvid can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tauvid.

This overview was last updated in 08-2024.