ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Tauvid 800 MBq/mL solution for injection
Tauvid 1 900 MBq/mL solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Tauvid 800 MBq/mL solution for injection

Each mL of solution for injection contains 800 MBq of flortaucipir (^{18}F) at the date and time of calibration (ToC).
The activity per vial ranges from 800 MBq to 12 000 MBq at the ToC in 1 mL to 15 mL.

Fluorine (^{18}F) decays to stable oxygen (^{18}O) with a half-life of approximately 110 minutes by emitting a positron radiation of 634 keV, followed by photonic annihilation radiation of 511 keV.

Excipients with known effect

Each mL of solution contains up to 79 mg of ethanol and 3.2 mg of sodium.
For the full list of excipients, see section 6.1.

Tauvid 1 900 MBq/mL solution for injection

Each mL of solution for injection contains 1 900 MBq of flortaucipir (^{18}F) at the date and time of calibration (ToC).
The activity per vial ranges from 1 900 MBq to 28 500 MBq at the ToC in 1 mL to 15 mL.

Fluorine (^{18}F) decays to stable oxygen (^{18}O) with a half-life of approximately 110 minutes by emitting a positron radiation of 634 keV, followed by photonic annihilation radiation of 511 keV.

Excipients with known effect

Each mL of solution contains up to 79 mg of ethanol and 3.4 mg of sodium.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection).
Clear, colourless solution.

Tauvid 800 MBq/mL solution for injection

The solution has a pH of 4.5 to 8.0 and an osmolality of approximately 2 356 mOsm/kg.

Tauvid 1 900 MBq/mL solution for injection

The solution has a pH of 6.0 to 8.0 and an osmolality of approximately 2 373 mOsm/kg.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Flortaucipir (^{18}F) is a radiopharmaceutical indicated for positron emission tomography (PET) imaging of the brain to assess the neocortical distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD). Flortaucipir (^{18}F) is an adjunct to clinical and other diagnostic evaluations.

For limitations of use, see sections 4.4 and 5.1.

4.2 Posology and method of administration

A PET scan with flortaucipir (^{18}F) should be requested by physicians skilled in the clinical management of neurodegenerative disorders.

Tauvid images should only be interpreted by readers trained in the interpretation of PET images with flortaucipir (^{18}F) (see section 4.4).

Posology

The recommended single intravenous dose is 370 MBq of flortaucipir (^{18}F) in a dose volume of ≤ 10 mL for an adult weighing 70 kg.

Special populations

Elderly
No dose adjustment is recommended based on age.

Renal and hepatic impairment
Flortaucipir (^{18}F) has not been studied in patients with current clinically significant renal or hepatic disease. An increase in radiation exposure is possible in patients with renal or hepatic disease, therefore careful consideration of the activity to be administered is required (see section 4.4).

Paediatric population
There is no relevant use of flortaucipir (^{18}F) in the paediatric population in the indication of PET imaging of the brain to assess the neocortical distribution of aggregated tau NFTs for the evaluation of the presence of AD.

Method of administration

Only authorised personnel qualified by training and experience should receive, store, dilute, and administer flortaucipir (^{18}F). Flortaucipir (^{18}F) should be used only in a designated nuclear medicine facility.

Flortaucipir (^{18}F) is for intravenous use.

Flortaucipir (^{18}F) is presented as a multidose vial.

The dose is administered by intravenous bolus injection, followed by a flush of up to approximately 10 mL of sodium chloride 9 mg/mL (0.9 %) solution for injection to ensure full delivery of the dose.

For instructions on dilution of the radiopharmaceutical before administration, see section 12. For patient preparation, see section 4.4.

Image acquisition

A 20 minute PET image should be acquired starting approximately 80 minutes after intravenous injection of flortaucipir (^{18}F). Patients should be supine with the head positioned to centre the brain, including the cerebellum, in the PET scanner field of view. Reducing head movement with tape or other flexible head restraints may be employed. Reconstruction should include attenuation correction. A recent co-registered computed tomography (CT) scan or magnetic resonance (MR) imaging of the patient to get a fused PET-CT or PET-MR image is recommended for anatomic localisation.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Individual benefit/risk justification

For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Limitations of use

A positive flortaucipir (^{18}F) scan cannot establish or refute a diagnosis of AD on its own and should only be used and interpreted in conjunction with clinical and other diagnostic evaluations (see section 4.1). Variable specificity observed suggests that false positives are possible (section 5.1). A negative flortaucipir (^{18}F) scan does not rule out the diagnosis of AD, or presence of earlier NFT pathology, e.g., B2 level.

Flortaucipir (^{18}F) performance for detecting tau pathology was assessed in terminally ill patients, the majority of whom had AD dementia with B3 level NFT pathology (see section 5.1). Flortaucipir (^{18}F) performance for detecting tau pathology may be lower in patients in earlier stages of the pathological spectrum.

Available data suggest that flortaucipir (^{18}F) is not informative in amyloid-negative patients, therefore in these patients the use of flortaucipir (^{18}F) is not recommended.

The efficacy of flortaucipir (^{18}F) for predicting or monitoring disease progression, or treatment effects has not been established (see section 5.1).

Flortaucipir (^{18}F) binds to AD-type neurofibrillary tangles. The safety and effectiveness of flortaucipir (^{18}F) to assess the distribution of tau resulting from chronic traumatic encephalopathy (CTE), non-AD type dementias, or neurodegenerative conditions have not been established.

Patient preparation

The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.

After the procedure

Close contact with infants and pregnant women should be restricted during the initial 4 hours following the injection.

Renal and hepatic impairment

Flortaucipir (^{18}F) is excreted through the hepatobiliary and renal systems. Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible (see section 4.2).

Interpretation of flortaucipir (^{18}F) images

Tauvid images should only be interpreted by readers trained in the interpretation of PET images with flortaucipir (^{18}F).

The goal of the read is to identify and locate areas of flortaucipir (^{18}F) activity in the neocortex that are greater than the background activity (background activity is defined as up to 1.65-fold the measured cerebellar average). For optimal display, select a colour scale with a rapid transition between two distinct colours and adjust the scale so that the transition occurs at the 1.65-fold threshold. Examine the posterolateral temporal (PLT), occipital, parietal, and frontal regions bilaterally. Neocortical activity in either hemisphere contributes to image interpretation. Activity in white matter, subcortical regions, or regions outside the brain (e.g. meninges, bone) may be seen, but does not contribute to image interpretation. To help identify the PLT region, consider subdividing the temporal lobe into four quadrants as instructed below. Activity in the anterior and medial temporal lobe may also be seen but it has not been established to be specific for AD and does not contribute to image interpretation of an AD flortaucipir (^{18}F) pattern.

Image display and orientation

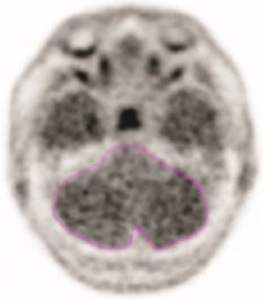
Display images in the transverse, sagittal, and coronal planes. Reorient images to remove head tilt in the transverse and coronal plane. Use a sagittal slice just off the midline to align the inferior frontal and inferior occipital poles in the horizontal plane.

Select and adjust the colour scale

To create a visual threshold for positivity:

- Draw a region of interest around the cerebellum in the transverse plane.
- Select the plane to go through the cerebellum at the maximum cross-sectional area of the cerebellum.
- Record the mean activity or cerebellar counts (MCC). The region of interest should be drawn with the scan in grey scale and in the transverse plane as seen in the example in figure 1.

Figure 1: Example of cerebellar region of interest



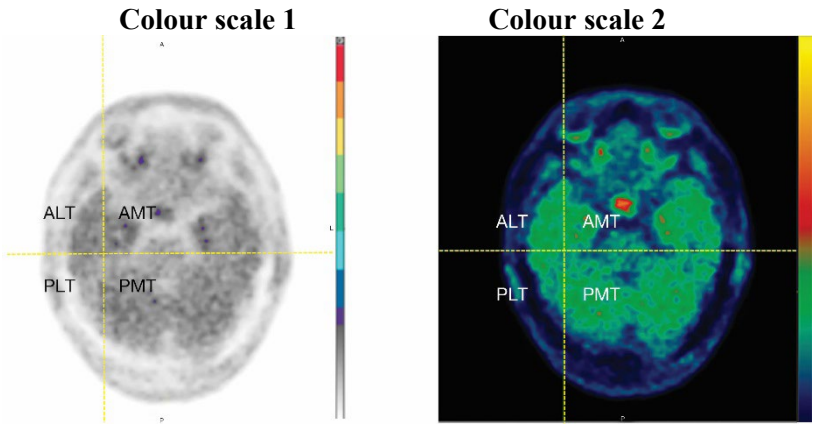
- Select a colour scale for image display that has a rapid transition between two distinct colours in the general range of 25 % to 60 % of maximum intensity.
- Set the upper contrast value (UCV) of the colour scale. Use the following formula to set the visual threshold of 1.65 × MCC to match the rapid transition in the colour scale:

UCV = (MCC × 1.65) x (100 % / % level of colour transition)

Preparation for image interpretation

- Before interpreting the image, review the brain to determine the lobar anatomy. Interpret the images by first evaluating the temporal lobes, followed by occipital, parietal, and frontal lobes bilaterally.
- To evaluate the temporal lobes, subdivide them into four quadrants by placing the horizontal crosshair immediately posterior to the brainstem nuclei and then scrolling inferiorly to place the vertical crosshair through the widest portion of the temporal pole, thus obtaining the anterolateral temporal (ALT), anterior mesial temporal (AMT), posterolateral temporal (PLT) and posterior mesial temporal (PMT) quadrants. See figure 2 for an example (the left and right image panels show the same scan in two different colour scales).

Figure 2: Temporal lobe quadrants



Potential image interpretation errors

Image interpretation errors can occur with flortaucipir (^{18}F) imaging. Interpret the PET flortaucipir (^{18}F) images based upon the pattern and density of the radioactive signal within the neocortical grey matter (not within white matter or in regions outside of the brain). Only uptake of tracer in the neocortical grey matter regions should contribute to scan interpretation.

Off-target binding may be seen in the choroid plexus, striatum, and brainstem nuclei. Small foci of non-contiguous tracer uptake may lead to false positive interpretation. Scans that have isolated or non-contiguous, small foci in any region should be interpreted with caution. Some scans may be difficult to interpret due to image noise or motion artifact. For cases where there is uncertainty as to the location of neocortical uptake, co-registered anatomical imaging should be used to improve localisation of uptake or for attenuation correction.

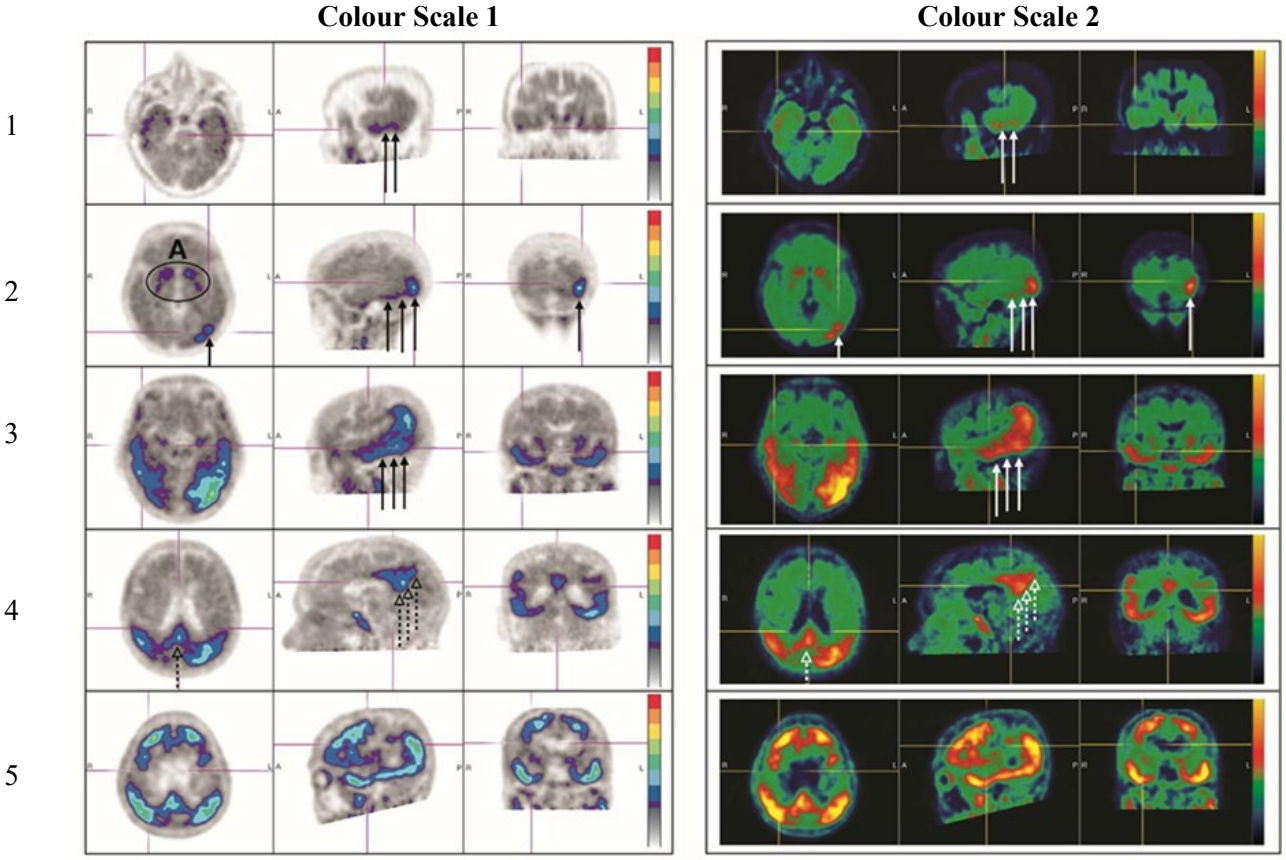
Positive flortaucipir (^{18}F) activity patterns supportive of AD diagnosis

Scans with increased neocortical activity in the posterolateral temporal (PLT), occipital, or parietal/precuneus region(s), with or without frontal region(s) activity, indicate the presence of tau B3 NFTs (tau pathology scoring; section 5.1). A flortaucipir (^{18}F) PET scan indicating the presence of B3 NFTs is supportive of an AD diagnosis in conjunction with clinical and other diagnostic evaluations. Neocortical activity in either hemisphere can contribute to identification of the pattern.

Positive AD flortaucipir (^{18}F) patterns fall into one of two categories:

- Moderate AD flortaucipir (^{18}F) pattern (figure 3, rows 1 and 2): increased neocortical activity in the PLT or occipital region(s).
- Advanced AD flortaucipir (^{18}F) pattern (figure 3, rows 3, 4, and 5): increased neocortical activity in the parietal/precuneus region(s), or increased activity in the frontal region(s) accompanied by increases in the PLT, parietal, or occipital region(s).

Figure 3. AD diagnostic scan examples

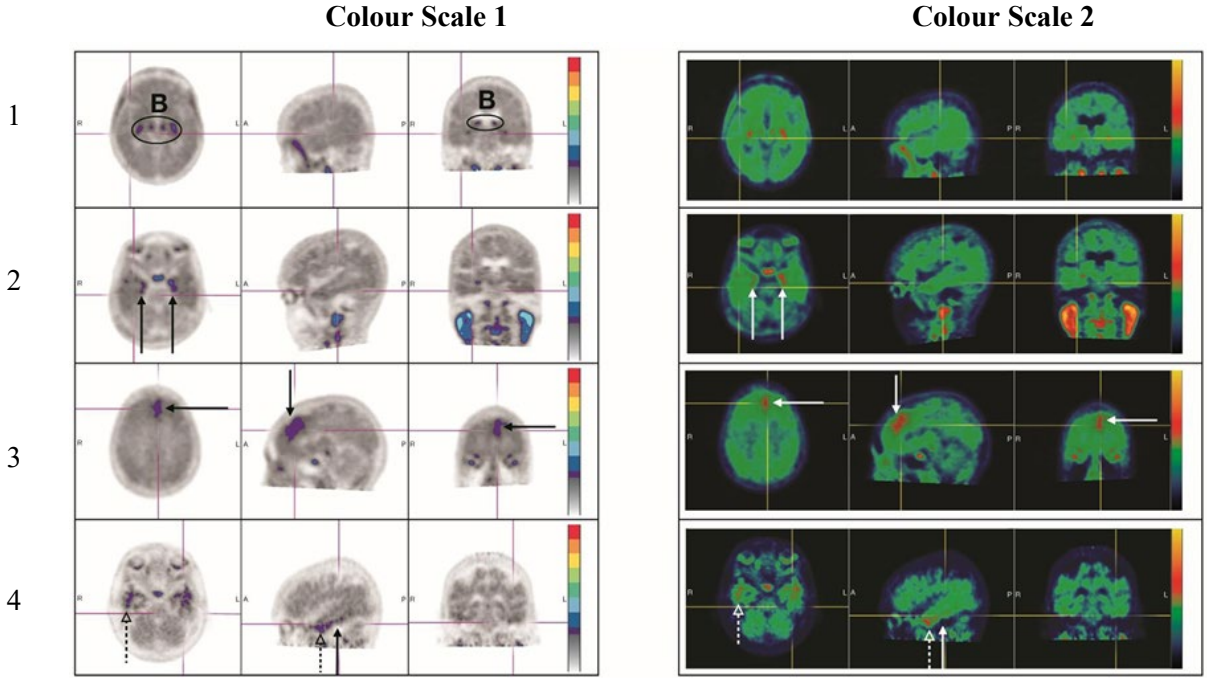


A: Off target binding in the striatum.
Row 1: Example of a patient with increased uptake in PLT (solid arrows).
Row 2: Example of a patient with increased uptake in PLT and occipital regions (solid arrows).
Row 3 and 4: Example of a patient with increased neocortical activity in PLT, occipital lobe (solid arrows) and precuneus (dashed arrows) (row 3: level of temporal lobes, row 4: level of parietal/precuneus).
Row 5: Example of a patient with increased neocortical activity in medial prefrontal/cingulate, lateral prefrontal, PLT, parietal, occipital and precuneus regions.

Negative flortaucipir (^{18}F) pattern

Scans without increased neocortical activity, or with increased neocortical activity isolated to the mesial temporal, anterolateral temporal, and/or frontal regions represent negative flortaucipir (^{18}F) patterns (figure 4).

Figure 4. Negative scan examples



B: Off target binding in the choroid plexus or brainstem nuclei.
Row 1: Example of a patient with no increased neocortical activity (activity is similar in intensity to cerebellar reference region).
Row 2: Example of a patient with increased activity isolated to MTL (solid arrows).
Row 3: Example of a patient with increased neocortical activity isolated to frontal lobe (solid arrows).
Row 4: Example of a patient with small, isolated foci of non-contiguous and variable uptake in the PLT (solid arrows); increased activity in the ALT (dashed arrows). This pattern may also be seen in the occipital or parietal region.

Excipients with known effect

Sodium

Tauvid 800 MBq/mL solution for injection contains up to 32 mg sodium per dose, equivalent to less than 2 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Tauvid 1 900 MBq/mL solution for injection contains up to 34 mg sodium per dose, equivalent to less than 2 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Ethanol

This medicinal product contains 790 mg of alcohol (ethanol) in each 10 mL dose, which is equivalent to 11.3 mg/kg (administered to an adult with 70 kg). The amount in 10 mL of this medicinal product is equivalent to less than 20 mL beer or 8 mL wine. The small amount of alcohol in this medicinal product will not have any noticeable effects.

For precautions with respect to environmental hazard see section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction

No *in vivo* interaction studies have been performed.

In vitro studies suggest that clinically meaningful changes in the pharmacokinetics of flortaucipir (^{18}F) are unlikely due to interactions at cytochrome enzymes or P-glycoprotein transporter. Similarly, flortaucipir (^{18}F) is not expected to affect the pharmacokinetics of other medicinal products.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

It is recommended that women of reproductive potential, unless using effective birth control, should abstain from intercourse for 24 hours (> 10 half-lives of radioactive decay for the ^{18}F isotope) following flortaucipir (^{18}F) administration.

Pregnancy

There are no available data on flortaucipir (^{18}F) use in pregnant women. No animal reproduction studies have been conducted with flortaucipir (^{18}F).
Radionuclide procedures carried out on pregnant women also involve radiation dose to the foetus. Any radiopharmaceutical, including flortaucipir (^{18}F), has a potential to cause foetal harm. Use of flortaucipir (^{18}F) is not recommended in pregnant women. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.

Breast-feeding

It is not known if flortaucipir (^{18}F) is excreted in human milk. Before administering radiopharmaceuticals to a mother who is breastfeeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breastfeeding should be interrupted for 24 hours and the expressed feeds discarded.

Close contact with infants, toddlers, children and pregnant women should be restricted during the initial 4 hours following injection.

Fertility

It is not known if flortaucipir (^{18}F) has any effect on fertility.

4.7 Effects on ability to drive and use machines

Tauvid has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions for flortaucipir (^{18}F) are headache (0.9 %), injection site pain (0.6 %), and blood pressure increased (0.5 %).

Tabulated list of adverse reactions

The safety profile of flortaucipir (^{18}F) is based on 4 652 subjects receiving one or more injections in clinical trials. The adverse reactions are listed below by SOC (system organ class) and by frequency, most frequent reactions first, with the following guidelines: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000).

Table 1. Adverse reactions observed with flortaucipir (^{18}F)

System organ class	Frequency and adverse reaction
Nervous system disorders	Uncommon: headache Uncommon: dysgeusia
General disorders and administration site conditions	Uncommon: injection site pain
Investigations	Uncommon: blood pressure increased[a]

[a]Includes hypertension, blood pressure systolic increased, and hypertensive urgency

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 9.6 mSv when the maximal recommended activity of 370 MBq is administered, these adverse reactions are expected to occur with a low probability.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Due to the small quantity of flortaucipir (^{18}F) in each vial, overdose is not expected to result in pharmacological effects. In the event of administration of a radiation overdose, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by frequent micturition and defaecation. It might be helpful to estimate the effective dose that was applied.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: diagnostic radiopharmaceutical, central nervous system, ATC code: V09AX07

Mechanism of action

Flortaucipir (^{18}F) binds to aggregated tau protein. In brains of patients with AD, paired helical filament (PHF) tau forms aggregates that combine to form neurofibrillary tangles (NFTs), a required

component of the neuropathological diagnosis of AD. *In vitro*, flortaucipir (^{18}F) binds to PHF tau purified from brain homogenates of donors with AD. Weak binding and poor colocalization was observed for tau aggregates from other non-AD tauopathies. *In vivo*, flortaucipir (^{18}F) is differentially retained in neocortical areas that contain aggregated tau. Flortaucipir (^{18}F) does not target amyloid.

Pharmacodynamic effects

At the chemical concentrations used for diagnostic examinations, flortaucipir (^{18}F) does not appear to have any pharmacological activity.

Clinical efficacy and safety

The efficacy and safety of flortaucipir (^{18}F) imaging were evaluated in a pivotal AD neuropathologic correlation study (Study 1) and an additional reader study (Study 2), and was supported by the published scientific literature.

In Study 1 and Study 2, the diagnostic performance of flortaucipir (^{18}F) imaging to estimate the distribution of aggregated tau NFTs was compared to post-mortem examination. In each study, 5 independent readers, who were blinded to clinical information, interpreted flortaucipir (^{18}F) imaging as positive or negative. Independent pathologists, who were blinded to clinical and imaging results, subsequently conducted post-mortem examination of the brains. The pathologists recorded tau NFT scores derived from Braak staging ranging from B0 to B3 (table 2).

Table 2. Tau pathology scoring

Tau pathology score	Distribution of Tau NFTs in the brain
B0	No NFTs
B1	NFTs limited to transentorhinal brain region
B2	B1 + NFTs limited to limbic brain regions
B3	B2 + NFTs distributed throughout the neocortex

In Study 1, reader interpretation of pre-mortem flortaucipir (^{18}F) scans from 64 terminally ill patients was compared to the findings from post-mortem brain examinations. Of the 64 patients, the mean age was 83 years (range 55 to 100); 34 were female; 49 had dementia, 1 had mild cognitive impairment, and 14 had no cognitive impairment on clinical evaluation around the time of flortaucipir (^{18}F) imaging. No formal neurological diagnosis was performed.

The study evaluated the performance of AD flortaucipir (^{18}F) pattern scans for distinguishing B3 (truth positive) from B0-B2 (truth negative) tau pathology.

Study 2 was a reader study that evaluated diagnostic performance of flortaucipir (^{18}F) imaging in 82 terminally ill patients (the same 64 patients from Study 1, plus 18 additional terminally ill patients). Sensitivity and specificity was investigated in scans from the terminally ill patients using the same neuropathology truth standard results recorded in Study 1.

The diagnostic performance of an AD flortaucipir (^{18}F) pattern to confirm the presence of AD-related NFTs from both studies is presented in table 3.

Table 3: Diagnostic performance of flortaucipir (^{18}F) scan among autopsied patients - Studies 1 and 2

Truth Standard	Study (N)	Sensitivity (%) (median and range)	Specificity (%) (median and range)
B3 NFT (Primary Analysis 1)	Study 1 (64)	92 (92 – 100)	76 (52 – 92)
	Study 2 (82)	89 (87 – 94)	77 (63 – 91)

In Study 1, for all cases with a visual read (whether or not the patient came to autopsy; n=105), Fleiss' kappa for inter-reader agreement across the 5 readers was 0.80 (95 % confidence interval 0.74 to 0.86). In Study 2, the Fleiss' kappa for all cases read including both scans from Study 1 autopsy subjects and scans from subjects with clinically defined MCI and AD (n=241) was 0.87 (95 % confidence interval 0.83 to 0.91).

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with Tauvid in all subsets of the paediatric population as the disease or condition for which the specific medicinal product is intended only occurs in adults (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Distribution

Flortaucipir (^{18}F) is distributed and metabolised rapidly throughout the body. Less than 10 % of the injected (^{18}F) radioactivity remains in blood 5 minutes after administration, and less than 5 % is present 10 minutes after administration.

Organ uptake

Maximum brain uptake of radioactivity occurs within several minutes of injection, followed by gradual region-specific brain clearance before approaching pseudo-equilibrium at approximately 80 minutes following injection.

Healthy controls show relatively low levels of flortaucipir (^{18}F) retention in the cortex and cerebellum. In amyloid-positive AD and MCI subjects, cortical regions show significantly greater uptake compared with cognitively normal controls. In AD and MCI subjects, as in controls, there is low retention in the cerebellum. In older controls who are amyloid negative, high retention in the choroid plexus, striatum, and brainstem nuclei has been observed and binding in these regions is presumed to be off-target.

Elimination

The residual flortaucipir (^{18}F) in circulation during the 80 to 100 minute imaging window is composed of approximately 28 %-34 % parent product with the remainder being metabolites.
Clearance occurs primarily by hepatobiliary and renal excretion.

Half-life

Flortaucipir (^{18}F) is very rapidly cleared from circulation post-intravenous injection. Plasma radioactivity (including parent flortaucipir (^{18}F) and all its metabolites) is below 10 % of the

theoretical maximum concentration by 5 minutes post-dose. The radioactive half-life of flortaucipir (^{18}F) is 110 minutes.

Renal/ Hepatic impairment

The pharmacokinetics in patients with renal or hepatic impairment have not been characterised.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, mutagenicity, or genotoxicity.

In vitro, flortaucipir (^{19}F) blocked the hERG channel, but with an IC_{50} exceeding the maximum theoretical peak human plasma concentrations by approximately 340-fold. Flortaucipir (^{19}F) did not induce QTc prolongation in dogs.

In an *in vitro* bacterial reverse mutation assay (Ames test), increases in the number of revertant colonies were observed in 4 of the 5 strains exposed to flortaucipir (^{19}F). In a chromosomal aberration *in vitro* study with Chinese hamster ovary (CHO) cells, flortaucipir (^{19}F) increased the percent of cells with structural aberrations with 3-hour exposure with or without activation. Twenty-hour exposure without activation produced an increase in structural aberrations at all tested concentrations.

Potential *in vivo* genotoxicity of flortaucipir was evaluated in a rat micronucleus study. In this assay, flortaucipir (^{19}F) did not increase the number of micronucleated polychromatic erythrocytes at the highest achievable dose level, 1 600 µg/kg/day, when given for 2 consecutive days.

No studies have been conducted in animals to investigate the potential carcinogenic, fertility or reproductive effects of flortaucipir (^{18}F).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tauvid 800 MBq/mL solution for injection

Anhydrous ethanol
Sodium chloride
Water for injections

Tauvid 1 900 MBq/mL solution for injection

Disodium phosphate (for pH adjustment)
Diluted hydrochloric acid
Anhydrous ethanol
Sodium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with medicinal products other than sodium chloride 9 mg/mL (0.9 %) solution for injection.

6.3 Shelf life

Chemical and physical in-use stability has been demonstrated for 7.5 hours (Tauvid 800 MBq/mL) and for 10 hours (Tauvid 1 900 MBq/mL) at 25°C. Product diluted according to the preparation described

in Section 12 must be used within 3 hours of dilution and prior to the radiopharmaceutical expiry, whichever is soonest.

From a microbiological point of view, unless the method of opening or dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.
Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

6.5 Nature and contents of container

Tauvid is supplied in 15 mL clear Type I borosilicate glass vial with chlorobutyl or fluropolymer-coated elastomeric stoppers and aluminium seals.

Tauvid 800 MBq/mL solution for injection

One multidose vial of 15 mL capacity contains 1 to 15 mL of solution corresponding to 800 to 12 000 MBq at ToC.

Tauvid 1 900 MBq/mL solution for injection

One multidose vial of 15 mL capacity contains 1 to 15 mL of solution corresponding to 1 900 to 28 500 MBq at ToC.

As a result of difference in the manufacturing processes it is possible that vials of some product batches are distributed with punctured rubber stoppers.

Each vial is enclosed in a shielded container of appropriate thickness to minimise external radiation exposure.

Pack size: 1 vial.

6.6 Special precautions for disposal and other handling

General warning

Radiopharmaceuticals should be received, stored, diluted, and administered only by authorised personnel in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken. For instructions on diluting the medicinal product before administration, see section 12.

If at any time in the preparation of this radiopharmaceutical the integrity of the vial is compromised it should not be used.

Administration procedures should be carried out in a way to minimise risk of contamination of the radiopharmaceutical and irradiation of the operators. Adequate shielding is mandatory.

The administration of radiopharmaceuticals creates risks for other persons (including pregnant healthcare professionals) from external radiation or contamination from spill of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

Any unused radiopharmaceutical or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83
3528 BJ Utrecht
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1799/001
EU/1/24/1799/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 August 2024

10. DATE OF REVISION OF THE TEXT

11. DOSIMETRY

The use of flortaucipir (^{18}F) requires the exposure of the patient to radiation. Based on biodistribution of flortaucipir (^{18}F) in the human body, organ radiation absorbed dose and the effective dose are shown below. The absorbed dose calculations for the reference adult male and female take into account the weighting factors (radiation and tissue) according to the recommendations of ICRP Publication 103. Due to a difference in the gastrointestinal tract structures, the time-integrated activity in the gastrointestinal structures was determined using the ICRP Publication 100 GI tract model in OLINDA. Time-integrated activity curves for all other source organs remained unchanged. Reference person equivalent doses were used to compute a reference person effective dose using equation B.3.9.

Table 4. Estimated radiation absorbed dose of flortaucipir (^{18}F)

	mGy/MBq	
Target Organ	**Reference Adult Male**	**Reference Adult Female**
Adrenals	0.02362	0.0242
Brain	0.00828	0.00946
Breasts	--	0.00890
Oesophagus	0.01344	0.01631
Eyes	0.0057	0.00702
Gallbladder Wall	0.04668	0.04749
Left Colon	0.05478	0.04606
Small Intestine	0.10391	0.12426
Stomach Wall	0.01388	0.01669
Right Colon	0.13027	0.12983
Rectum	0.01963	0.01831
Heart Wall	0.03124	0.03731
Kidneys	0.04102	0.04726
Liver	0.06203	0.07666
Lungs	0.03047	0.03728
Ovaries	--	0.01617
Pancreas	0.02217	0.02616
Prostate	0.01208	--
Salivary Glands	0.00671	0.00767
Red Marrow	0.00950	0.01186
Osteogenic Cells	0.00846	0.00967
Spleen	0.01148	0.01494
Testes	0.00654	--
Thymus	0.01093	0.01393
Thyroid	0.00855	0.00968
Urinary Bladder Wall	0.03757	0.04341
Uterus	--	0.01867
Total Body	0.01079	0.01506
Effective Dose 0.02598 mSv/MBq		

Thus, the effective dose resulting from the administration of a (maximal recommended) activity of 370 MBq for an adult weighing 70 kg is about 9.6 mSv. If a Computerised Tomography (CT) scan is simultaneously performed as part of the PET procedure, exposure to ionising radiation will increase in an amount dependent on the settings used in the CT acquisition. For an administered activity of 370 MBq the typical radiation dose to the target organ [brain] is 3.1 mGy and the typical radiation dose/doses to the critical organ/organs [right colon, small intestine, liver] are 48.2 mGy, 38.4 mGy, and 23.0 mGy respectively.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

The package must be checked before use and the activity measured using an activimeter.

Withdrawals should be performed under aseptic conditions. The vials must not be opened before disinfecting the stopper, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorised automated application system. If the integrity of this vial is compromised, the product should not be used. For special handling precautions see section 6.6.

Method of preparation

If a larger volume is needed at the time of dose administration, flortaucipir (^{18}F) solution for injection may be diluted aseptically with sodium chloride 9 mg/mL (0.9 %) solution for injection to a maximum dilution of 1:5 prior to administration, e.g., combine 0.5 mL flortaucipir (^{18}F) solution and 2 mL sodium chloride 9 mg/mL (0.9 %) solution for injection. Diluted product must be used within 3 hours of dilution and prior to the radiopharmaceutical expiry, whichever is soonest.

Quality control

The radiopharmaceutical dose should be measured by a suitable radioactivity measurement system and inspected for particulate matter or discolouration prior to administration. Only clear solutions, free of visible particles should be used.

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Curium Pet France
14 Rue De La Grange Aux Belles
75010 Paris,
France

Alliance Medical RP Berlin GmbH
Max-Planck-Straße 4
12489 Berlin
Germany

Alliance Medical RP GmbH
Spessartstraße 9
53119 Bonn
Germany

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;

- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

SHIELD LABEL

1. NAME OF THE MEDICINAL PRODUCT

Tauvid 800 MBq/mL solution for injection
flortaucipir (^{18}F)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each mL of solution for injection contains 800 MBq of flortaucipir (^{18}F) at date and time of calibration (ToC).

3. LIST OF EXCIPIENTS

Excipients: Anhydrous ethanol, sodium chloride, water for injections.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
1 vial
Volume: {Z} mL
Activity: {Y} MBq in {Z}mL
ToC: {DD/MM/YYYY} {hh:mm}{Time Zone}
Vial No

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Multidose vial
Read the package leaflet before use.
Intravenous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

7. OTHER SPECIAL WARNING(S), IF NECESSARY

☢
Radioactive material

8. EXPIRY DATE

EXP {DD/MM/YYYY} {hh:mm}{Time Zone}

9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special temperature storage conditions.
Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1799/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Tauvid 800 MBq/mL injection
flortaucipir (^{18}F)
Intravenous use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.
Multidose vial

3. EXPIRY DATE

EXP: ToC + 7.5 h

4. BATCH NUMBER

Lot
Vial No

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

≤ 12 000 MBq at ToC (see outer packaging)

6. OTHER

Curium Pet France, 75010, Paris, France

Alliance Medical RP Berlin GmbH, 12489, Berlin, Germany

Alliance Medical RP GmbH, 53119, Bonn, Germany

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

SHIELD LABEL

1. NAME OF THE MEDICINAL PRODUCT

Tauvid 1 900 MBq/mL solution for injection
flortaucipir (^{18}F)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each mL of solution for injection contains 1 900 MBq of flortaucipir (^{18}F) at date and time of calibration (ToC).

3. LIST OF EXCIPIENTS

Excipients: Disodium phosphate (for pH adjustment), diluted hydrochloric acid, anhydrous ethanol, sodium chloride, water for injections.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
1 vial
Volume: {Z} mL
Activity: {Y} MBq in {Z}mL
ToC: {DD/MM/YYYY} {hh:mm}{Time Zone}
Vial No

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Multidose vial
Read the package leaflet before use.
Intravenous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

7. OTHER SPECIAL WARNING(S), IF NECESSARY

☢
Radioactive material

8. EXPIRY DATE

EXP {DD/MM/YYYY} {hh:mm}{Time Zone}

9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special temperature storage conditions.
Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1799/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Tauvid 1 900 MBq/mL injection
flortaucipir (^{18}F)
Intravenous use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.
Multidose vial

3. EXPIRY DATE

EXP: ToC + 10 h

4. BATCH NUMBER

Lot
Vial No

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

≤ 28 500 MBq at ToC (see outer packaging)

6. OTHER

Curium Pet France, 75010, Paris, France

Alliance Medical RP Berlin GmbH, 12489, Berlin, Germany

Alliance Medical RP GmbH, 53119, Bonn, Germany

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Tauvid 800 MBq/mL solution for injection
Tauvid 1 900 MBq/mL solution for injection
flortaucipir (^{18}F)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tauvid is and what it is used for

This medicine is a radiopharmaceutical (radioactive medicine) for diagnostic use only. Tauvid contains the active substance flortaucipir (^{18}F).

Tauvid is given to adults with memory problems who are being evaluated for Alzheimer's disease so that doctors can perform a type of brain scan, called a PET (Positron Emission Tomography) scan. A PET scan, along with other brain function tests, may help your doctor find the reason for your memory problems. Tauvid can help your doctor determine whether or not you may have abnormal forms of tau protein in your brain. Abnormal forms of tau protein are present in the brains of people with Alzheimer's disease.

The use of Tauvid involves exposure to radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation (see section 3).

2. What you need to know before Tauvid is used

Tauvid must not be used
- if you are allergic to flortaucipir (^{18}F) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before you are administered Tauvid
- if you have liver or kidney problems, as an increase in radiation exposure is possible
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding (see section 2, "pregnancy, breastfeeding and fertility").

Before administration of Tauvid you should
Drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study.

Children and adolescents
There is no relevant use of Tauvid in children and adolescents as it is intended to be used in adults with memory problems who are being evaluated for Alzheimer's disease.

Other medicines and Tauvid
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of Tauvid if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding. When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant
Any radiopharmaceutical, including Tauvid, has a potential to harm the unborn baby. Use of Tauvid is not recommended in pregnant women. The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding
The use of Tauvid is not recommended while breastfeeding. You must stop breast-feeding for 24 hours after the injection and the breast milk pumped must be discarded. Please ask your nuclear medicine doctor when you can resume breast-feeding (see section 3, "after administration of Tauvid, you should").

Driving and using machines
It is considered unlikely that Tauvid will affect your ability to drive or to use machines.

Tauvid 800 MBq/mL and 1 900 MBq/mL contains ethanol
This medicine contains 790 mg of alcohol (ethanol) per dose, which is comparable to less than 20 mL beer or 8 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Tauvid contains sodium
Tauvid 800 MBq/mL solution for injection contains up to 32 mg sodium (main component of cooking / table salt) in each dose. This is 1.6 % of the recommended maximum daily dietary intake of sodium for an adult.

Tauvid 1 900 MBq/mL solution for injection contains up to 34 mg sodium (main component of cooking / table salt) in each dose. This is 1.7 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Tauvid is used

There are strict laws on the use, handling and disposal of radiopharmaceuticals. Tauvid will only be used in special controlled areas. This medicine will only be handled and given to you by people who are trained and qualified to use it safely. Qualified personnel will take special care for the safe use of this radiopharmaceutical and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the amount of Tauvid to be used in your case. It will be the smallest amount necessary to get the desired information from the PET

scan. The usual amount recommended for an adult is 370 MBq. Megabecquerel (MBq) is the unit used to express radioactivity.

Administration of Tauvid and conduct of the procedure
Drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study. Tauvid is administered as an injection into your vein followed by another injection into your vein with sodium chloride solution to ensure that you receive the full dose of Tauvid.

One injection of flortaucipir (^{18}F) is sufficient to conduct the brain scan.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure. A brain scan lasts 20 minutes and is usually done about 80 to 100 minutes after you are given Tauvid.

After administration of Tauvid, you should:
- Avoid any close contact with infants, toddlers, children and pregnant women for 4 hours following the injection.

The nuclear medicine doctor will recommend you to void as often as possible during the first hours after the examination in order to reduce radiation. Contact your nuclear medicine doctor if you have any questions.

If you have been given more Tauvid than you should
An overdose is unlikely because you will only receive a single dose of Tauvid precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.

Should you have any further question on the use of Tauvid, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon (may affect up to 1 in 100 people):
- headache
- dysgeusia (altered taste)
- pain where the injection is given
- increased blood pressure

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities (see section 1, “what Tauvid is and what it is used for”).

Reporting of side effects
If you get any side effects talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Tauvid is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.
Tauvid must not be used after the expiry date which is stated on the shield and vial label after EXP.

Tauvid must not be administrated if it is noticed particulate matter or discolouration.

This medicinal product does not require any special temperature storage conditions.

6. Contents of the pack and other information

What Tauvid contains

- The active substance is flortaucipir (^{18}F).
  Tauvid 800 MBq/mL solution for injection: 1 mL of solution for injection contains 800 MBq of flortaucipir (^{18}F) at the date and time of calibration.
  Tauvid 1 900 MBq/mL solution for injection: 1 mL of solution for injection contains 1 900 MBq of flortaucipir (^{18}F) at the date and time of calibration.
- The other ingredients are
  Tauvid 800 MBq/mL solution for injection: anhydrous ethanol, sodium chloride, water for injections (see section 2 “Tauvid contains ethanol and sodium”).
  Tauvid 1 900 MBq/mL solution for injection: anhydrous ethanol, disodium phosphate (for pH adjustment), diluted hydrochloric acid, sodium chloride, water for injections (see section 2 “Tauvid contains ethanol and sodium”).

What Tauvid looks like and contents of the pack
Tauvid is a clear, colourless solution for injection. It is supplied in a 15 mL clear glass vial.

Tauvid 800 MBq/mL solution for injection (injection): One multidose vial of 15 mL capacity containing 1 to 15 mL of solution, corresponding to 800 to 12 000 MBq at date and time of calibration.

Tauvid 1 900 MBq/mL solution for injection (injection): One multidose vial of 15 mL capacity containing 1 to 15 mL of solution, corresponding to 1 900 to 28 500 MBq at date and time of calibration.

Marketing Authorisation Holder
Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands

Manufacturer
Curium Pet France
14 Rue De La Grange Aux Belles
75010 Paris,
France

Alliance Medical RP Berlin GmbH
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12489 Berlin
Germany

Alliance Medical RP GmbH
Spessartstraße 9
53119 Bonn
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

The complete Summary of Product Characteristics (SmPC) of Tauvid is provided in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical. Please refer to the SmPC [SmPC should be included in the box].