IASOglio®
Fluoroethyl-L tyrosine (^{18}F)

Marketing Authorisation country

Country	1st Marketing Authorisation	Marketing Authorisation Number
France	23.12.2015	34009 550 105 1 7 (15 mL); 34009 550 105 2 4 (25 mL)

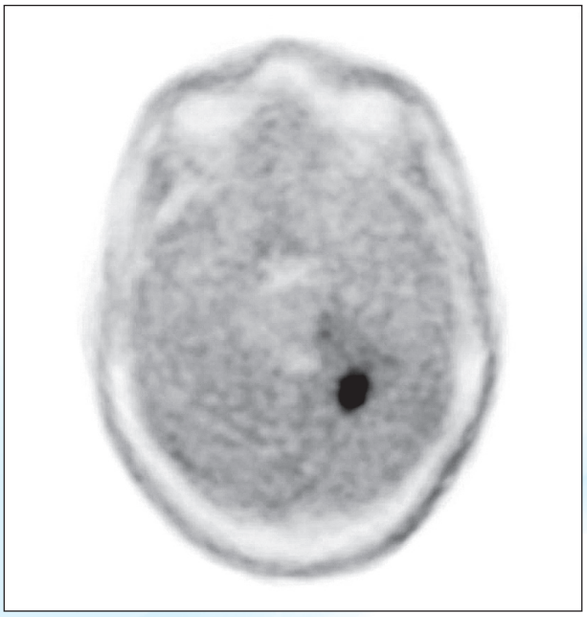
CLINICAL PARTICULARS

1. Therapeutic indications

This medicinal product is for diagnostic use only. IASOglio is indicated for use with positron emission tomography (PET). IASOglio is used for imaging in patients undergoing oncologic diagnostic procedures describing functions or diseases where enhanced amino acid influx of specific organs or tissues is the diagnostic target.

The following indications have been particularly documented:

- Characterisation of brain lesions suggestive of glioma
- Selecting the best biopsy site in brain lesion suggestive of glioma
- Non-invasive grading of glioma
- Pre therapeutic delineation of viable glioma tissue
- After treatment: detection of viable tumour tissue in case of suspicion of persistent or recurrent glioma.



IASOglio PET/CT scan:
Patient with recurrent glioma

Courtesy of: Chiara M Grana, MD & Marzia Colandrea, MD; Division of Nuclear Medicine; European Institute of Oncology; Milano, Italy

2. Posology and method of administration

Posology

Adults and elderly
The recommended activity for an adult weighing 70 kg is 180 to 250 MBq (the activity will be adapted to the body mass, the type of camera used, PET/CT, and acquisition mode), administered by direct intravenous injection.

Special populations
Patients with renal impairment. Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Paediatric population
The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and adolescents may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) for paediatric task group Dosage Card; the activity administered to children and to adolescents may be calculated by multiplying a baseline activity (for calculation purposes) by the weight-dependent multiples given in the table below.
When 3D TEP acquisition mode is available, which is highly recommended:
$A(MBq)_{Administered}$ = 14 × Multiple (see table below), minimum activity = 14 MBq.

When only 2D TEP acquisition mode is available :
$A(MBq)_{Administered}$ = 25.9 × Multiple (see table below), minimum activity = 26 MBq.

Weight (kg)	Multiple	Weight (kg)	Multiple	Weight (kg)	Multiple
3	1.00	**22**	5.29	**42**	9.14
4	1.14	**24**	5.71	**44**	9.57
6	1.71	**26**	6.14	**46**	10.00
8	2.14	**28**	6.43	**48**	10.29
10	2.71	**30**	6.86	**50**	10.71
12	3.14	**32**	7.29	**52-54**	11.29
14	3.57	**34**	7.72	**56-58**	12.00
16	4.00	**36**	8.00	**60-62**	12.71
18	4.43	**38**	8.43	**64-66**	13.43
20	4.86	**40**	8.86	**68**	14.00

Method of administration
For intravenous use.
For multidose use.
The activity of IASOglio has to be measured with an activimeter immediately prior to injection

Precautions to be taken before handling or administration of the medicinal product
For instructions on the dilution of the medicinal product before administration, see section 12.
For patient preparation, see section 4.
The injection of IASOglio must be intravenous in order to avoid irradiation as a result of localextravasation, as well as imaging artefacts.

Image acquisition
– Dynamic acquisition of PET images of the brain during 40 minutes starting immediately after injection.
– Or one static PET acquisition starting 20 to 40 minutes after injection.

3. Contraindications
– Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
– Pregnancy (see section 6)

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.

Renal impairment
Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

Paediatric population
For information on the use in paediatric population, see sections 2.
Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11).

Patient preparation
IASOglio should be administered to patients fasting for a minimum of 4 hours.
In order to obtain images of best quality and to reduce the radiation exposure of the bladder, patients should be encouraged to drink sufficient amounts and to empty their bladder prior to and after the PET examination.

After the procedure
Close contact with infants and pregnant women should be restricted during 12 hours following the injection.

Specific warnings
Depending on the time when you administer the injection, the content of sodium given to the patient may in some cases be greater than 1 mmol (23 mg). This should be taken into account in patients on low sodium diet.
This medicinal product contains 10% ethanol, i.e. up to 0.8 g per maximum volume of 10 mL. This amount will produce a blood alcohol concentration of 0.02 g/L (2 mg/100 mL) for an adult weighing 70 kg. This is equivalent to 20 mL beer or 8 mL wine per maximum dose. This should be taken into account in patients suffering from alcoholism, breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.
Precautions with respect to environmental hazard are in section 6.6.
The maximum volume to be administered to a patient should not exceed 10 mL.

5. Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

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.

Pregnancy
The use of IASOglio is contraindicated in pregnant women due to the radiation exposure to the foetus (see section 3).

Breastfeeding
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 12 hours and the expressed feeds discarded.
Close contact with infants should be restricted during this period.

Fertility
No studies on fertility have been performed.

7. Effects on ability to drive and use machines
Not relevant.

8. Undesirable effects
Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 4 mSv when the maximal recommended activity of 250 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 reaction via the national reporting system.

9. Overdose
In the event of administration of a radiation overdose with IASOglio the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. It might be helpful to estimate the effective dose that was applied.

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