IASOflu®
[18F] sodium fluoride

Marketing Authorisation countries

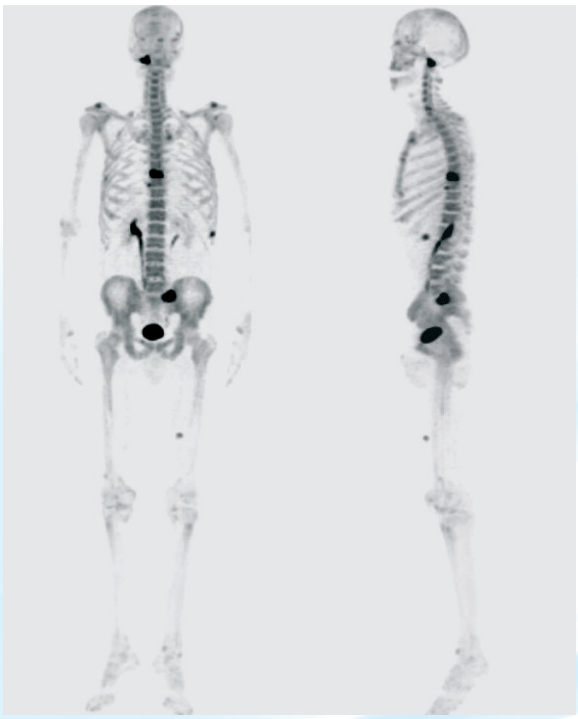
Countries	1st Marketing Authorisation	Marketing Authorisation number
France	21.07.2008	34009 578 426 5 9 (15ml) ; 34009 573 228 0 9 (25ml)
Austria	20.10.2010	4-00043
Belgium	11.10.2010	BE379102 (15 ml) ; BE379111(25 ml)
Bulgaria	22.10.2010	II-11061/22.10.2010
Germany	22.11.2010	76609.00.00
Hungary	28.04.2011	OGYI-T-21705/01 (15 ml) ; OGYI-T-21705/02 (25 ml)
Italy	14.10.2013	040986010 (15 ml) ; 040986022 (25 ml)
Luxembourg	17.06.2011	1523/11050028
Poland	20.01.2011	17727
Romania	13.05.2011	8035/2015/01-02
Slovakia	31.01.2011	88/0832/10-S
Slovenia	24.02.2011	H/11/00747/001 (15 ml) ; H/11/00747/002 (25 ml)

CLINICAL PARTICULARS

This medicinal product is for diagnostic use only.

Sodium fluoride (^{18}F) positron emission tomography (PET) is indicated for functional imaging in diseases where abnormally altered osteogenic activity is the diagnostic target. The following indications have been particularly documented:

- Detection and localisation of bone metastases in case of cancer in adults.
- As an aid in the evaluation of back pain of ambiguous origin in adults, when conventional imaging modalities are not conclusive.
- As an aid in the detection of the presence of bone lesions related to suspected child abuse.



IASOflu® PET/CT scan:
Colon cancer patient with bony metastases. Collateral finding: left thigh soft tissue calcification

Courtesy of: Carlo L. Maini, MD, PhD; Nuclear Medicine Department; "Regina Elena" National Cancer Institute; Roma; Italy

4. CLINICAL PARTICULARS
4.2. Posology and method of administration
Posology
Adults
The recommended activity for an adult weighing 70 kg is 370 MBq (the activity will be adapted to the body mass, the type of camera used, PET/CT, and acquisition mode. The activity could vary from 100–400 MBq, administered by direct intravenous injection.
If required, sodium fluoride (^{18}F) PET examinations can be repeated within a short period of time.
Special populations
Patients with renal impairment
In case of renal impairment, exposure to ionising radiation can be increased. This must be taken into account when calculating the activity to be administered.
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 EANM 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 body-mass-dependent coefficients given in the table below.

A[MBq]Administered = Baseline Activity × Coefficient

A minimum activity of 14 MBq is recommended in case of acquisition with 3D PET system and 26 MBq in the case of acquisition with 2D PET system. In children images acquisition in 3D mode should be preferred

Weight [kg]	Multiple	Weight [kg]	Multiple	Weight [kg]	Multiple
3	1	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.
Precautions to be taken before handling or administration of the medicinal product
For instructions on dilution of the medicinal product before administration, see section 12. For patient preparation, see section 4.4.
The activity of sodium fluoride (^{18}F) has to be measured with an activimeter immediately prior to injection. The injection must be intravenous in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts.
Image acquisition
The emission scans are usually started 60 minutes after the injection of sodium fluoride (^{18}F). Provided a sufficient activity remains for adequate counting statistics, sodium fluoride (^{18}F)-PET scans can also be performed up to two or three hours after administration, thus reducing background activity. Voiding immediately prior to imaging is recommended in order to reduce the activity in the pelvis.
4.3. Contraindications
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pregnancy (see section 4.6).

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.
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 section 4.2.
Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11).
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 study in order to reduce radiation.
Interpretation of sodium fluoride (^{18}F)-PET images
Sodium fluoride (^{18}F) has a higher sensitivity for the detection of bone lesions than other "bone-seeking" tracers (^{99m}Tc-labelled phosphate and phosphonic acid derivatives). Since sodium fluoride (^{18}F) does not show secondary cancerous processes directly, but notifies cancer effects (osteogenic activity following osseous lesions), sodium fluoride (^{18}F) is less effective for the detection of early stages of bone metastases, like bone marrow metastases without substantial bone damage. Hardware fusion of the functional sodium fluoride (^{18}F) PET images with morphologic images e.g. PET-CT can lead to an increased sensitivity and specificity in bone diagnostics.
As there is no significant difference in uptake by malignant or benign lesions, the differentiation between bone metastases and non-malignant bone lesions benefits from the analysis of PET and CT image fusion, better obtained from hybrid PET-CT imaging, or if not available from supplemental diagnostic procedures (MRI, CT).
After the procedure
Close contact with infants and pregnant women should be restricted during the initial 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 patient on low sodium diet.
Precautions with respect to environmental hazard are in section 6.6.
4.5. Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.
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.
Pregnancy
The use of sodium fluoride (18F) is contraindicated in pregnant women due to the radiation exposure to the foetus (see section 4.3).
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 the initial 12 hours following injection.
Fertility
No studies on fertility have been performed.
4.7. Effects on ability to drive and use machines
Not relevant.
4.8. Undesirable effects
Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 6.8 mSv when the maximal recommended activity of 400 MBq is administered for an adult of 70 kg, 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.
4.9. Overdose
In the event of administration of a radiation overdose with sodium fluoride (^{18}F) 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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