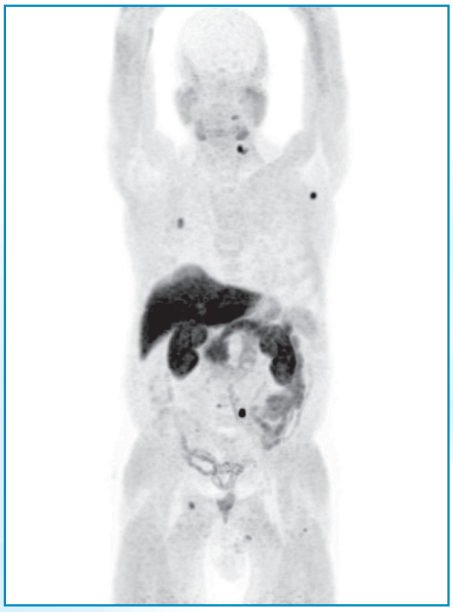
IASOcholine® 1 GBq/mL, solution for injection
fluoromethyl-(^{18}F)-dimethyl-2-hydroxyethyl-ammonium chloride

Marketing Authorisation countries

Countries	1st Marketing Authorisation	Marketing Authorisation number
France	02.04.2010	34009 578 253 3 1 (15 ml); 34009 576 946 1 6 (25 ml)
Austria	25.08.2011	4-00044
Belgium	08.07.2013	BE440176 (15 ml); BE440185 (25 ml)
Bulgaria	20.09.2012	II-19591/20.09.12
Czech Republic	14.11.2012	88/651/12-C
Estonia	29.08.2012	792812
Germany	19.07.2011	81779.00.00
Italy	03.02.2014	043096015 (15 ml); 043096027 (25 ml)
Lithuania	17.12.2012	LT/1/12/3159/001 (15 ml); LT/1/12/3159/002 (25 ml)
Luxembourg	01.08.2013	2013080285
Malta	26.04.2013	MA 986/00101
Poland	31.07.2012	20446
Romania	17.10.2012	8391/2015/01-02
Slovakia	05.12.2012	88/0527/12-S
Slovenia	11.07.2012	H/12/00746/001 (15 ml); H/12/00746/002 (25 ml)



IASOcholine® PET/CT scan:
Patient with metastatic prostate cancer

Courtesy of: Dr. Giuseppe Trifirò; Nuclear Medicine Unit; ICS Maugeri Pavia; Pavia-Italy

CLINICAL PARTICULARS

This medicinal product is for diagnostic use only. Fluorocholine (^{18}F) chloride is indicated for use with positron emission tomography (PET).

IASOcholine® is used for imaging in patients undergoing oncologic diagnostic procedures describing function or diseases where enhanced choline influx of specific organs or tissues is the diagnostic target.

The following indications for PET with fluorocholine (^{18}F) chloride have been sufficiently documented:

Prostate cancer
Detection of bone metastases of prostate cancer in high risk patients.

Hepatocellular carcinoma
- Localisation of lesions of proven well-differentiated hepatocellular carcinoma.
- In addition to FDG PET, characterisation of liver nodes and/or staging of proven or very likely hepatocellular carcinoma, when FDG PET is non conclusive or when surgery or grafting is scheduled.

CLINICAL PARTICULARS

4.2. Posology and method of administration
Posology
Adults and elderly
The recommended activity for an adult weighting 70 kg is 200 to 500 MBq administered by direct intravenous injection. This activity has to be adapted according to the body weight of the patient and the type of PET or PET/CT camera used.
Renal impairment
Extensive dose-range and adjustment studies with this product in normal and special populations have not been performed. The pharmacokinetics of (18F) in renally impaired patients has not been characterised.
Paediatric population
No clinical data are available for patients aged less than 18 years concerning safety and diagnostic efficacy of the product. Therefore, the use in oncologic paediatrics is not recommended.
Method of administration
For patient preparation, see section 4.4.
The activity of fluorocholine (^{18}F) chloride has to be measured with activimeter immediately prior to injection.
The injection of fluorocholine (^{18}F) chloride must be intravenous in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts. It should be administered by direct intravenous injection.
Image acquisition
For prostate cancer: dynamic PET acquisition over the pelvis including the prostate bed and the pelvic bones, during 8 min, starting 1 min after injection, or if not feasible one 2 min static acquisition starting 1 min post injection.
For all indications: "Static" whole-body PET acquisition started 10 to 20 min after injection. If there is doubt concerning lesions with a slow uptake (e.g. negative static images whereas serum PSA levels are increased), a second static acquisition may be performed after one hour.
4.3. Contraindications
- Hypersensitivity to the active substance, to any of the excipients or to any of the components of the labelled radiopharmaceutical.
- Pregnancy.

4.4. Special warnings and precautions for use
Pregnancy, see section 4.3 and 4.6
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 indication is required since an increased radiation exposure is possible in these patients.
Paediatric population
For information on the use in paediatric population, see section 4.2. or 5.1.
Patient preparation
IASOcholine® should be given 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 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. This should be taken into account in patient on low sodium diet.
Precautions with respect to environmental hazard see section 6.6.
The maximum volume to be administered to a patient should not exceed 10 mL.
4.5. Interaction with other medicinal products and other forms of interaction
In patients receiving anti-androgen therapy, the indication of IASOcholine® PET must be particularly documented by rising serum PSA levels. Any recent change in therapy must lead to the revision of the IASOcholine® PET indication taking into consideration the expected impact on patient management.
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 IASOcholine® is contraindicated in pregnant women due to the radiation doses to the foetus (see section 4.3).
No data are available concerning the use of this product during pregnancy. No studies of reproductive function have been performed in animals.
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 the initial 12 hours following injection and the expressed feeds discarded.
Close contact with infants should be restricted during this period.
4.7. Effects on ability to drive and use machines
Not relevant.
4.8 Undesirable effects
No undesirable effects have been observed to date. Since the administered substance quantity is very low, the major risk is caused by the radiation. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects As the effective dose is 5.6 mSv when the maximal recommended activity of 280 MBq (4MBq/kg for a subject weighting 70kg) is administered these adverse events 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
An overdose in the pharmacological sense is unlikely given with the doses used for diagnostic purposes. In the event of administration of a radiation overdose with fluorocholine (18F) chloride 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.

P04-E-112017-V07

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