Radiopharmaceuticals Division of ÚJV Řež

The mission of the Radiopharmaceuticals Division is to produce medicinal products of top European quality and to develop new products based on advanced technologies.

Our Services

Comprehensive PET Centre Construction Services

Our long-term and unique experience in this field allows us to provide the following services during PET centre construction:

- Consultancy for the implementation of pharmaceutical production
- Preparation of complete project documentation (construction and technology)
- Selection of suitable suppliers
- Acceptance tests and commissioning
- Assistance in obtaining the necessary permits and certificates for operation
- Comprehensive training system for PET equipment operators

Manufacturing of Investigational Medicinal Products

- The Division holds all necessary permits and certificates
- It possesses appropriate premises, technology, and highly skilled personnel.

Quality Control

Established chemical and physical control processes under the GMP (Good Manufacturing Practice cover the fields of PET radiopharmaceutical products, as well as other pharmaceutical raw material materials.

Distribution of Medicines

For the purposes of distribution, transport, and sale of medicines within the Czech Republic, we hold a Good Distribution Practice (GDP) certificate. We possess the necessary permits for handling ionising radiation, and our monitored vehicles and drivers are subject to ADR rules (European Agreement concerning the International Carriage of Dangerous Goods by Road).

Performance of Qualified Person (QP) Activities

We have a sufficient number of experienced qualified persons with a high-level of expertise and education, capable of ensuring the release of medicines for sale.

Certificates and Permits

- Authorisation for the Manufacture of Medicinal and Investigational Medicinal Products
- Authorisation for the Distribution of Medicinal Products
- Certificate of Good Manufacturing Practice for Manufacturers—Human Medicinal Products
- Certificate of Good Manufacturing Practice for Manufacturers—Human Investigational Medicinal Products
- SÚJB (State Office for Nuclear Safety) Permit for Handling Ionising Radiation Sources
- ISO 9001, ISO 14001, ISO 45001

Product Overview

Product Name
Fludeoxyglucose 100 – 1500 MBq/ml solution for injection

Marketing Authorisation Number
88/320/01-C

Pharmacotherapeutic Group

Diagnostic radiopharmaceuticals; tumour detection, other diagnostic radiopharmaceuticals; ATC code: V09IX04

Active Substance

Fludeoxyglucosum (^{18}F) 100–1,500 MBq/ml at the date and time of calibration; fluorine (^{18}F) has a half-life of 110 minutes

Pharmaceutical Form

Clear, colourless solution for injection, free of particles

Indications

Fludeoxyglucose (^{18}F) is for diagnostic use only; it is indicated for use in conjunction with positron emission tomography (PET) in adults and in the paediatric population.

- **Oncology***:* In patients undergoing oncological examinations of functions or diseases, where the diagnostic objective is imaging of increased glucose uptake in specific organs or tissues. For documented indications, see the full text of the Summary of Product Characteristics.
- **Cardiology:** Assessment of myocardial tissue viability.
- **Neurology:** Interictal glucose metabolism, localisation of epileptogenic foci.
- **Infectious or inflammatory diseases:** The diagnostic target is tissue or structures with an abnormal accumulation of activated white blood cells.

See the full Summary of Product Characteristics for detailed information on indications.

Method of Administration

Fludeoxyglucose is administered as a single intravenous injection.

Shelf Life

8 hours from the reference date and time

Storage

Store below 25°C in the original closed containers, in accordance with regulations on health protection against ionising radiation.

Packaging

- Inner packaging: Injection vial (10 ml or 20 ml) made of Class I hydrolytic glass, closed with a rubber stopper and a metal seal
- Outer packaging: Lead, tungsten, or uranium container

Pack Size

0.5; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5; 5.5; 6; 6.5; 7; 7.5; 8; 8.5; 9; 9.5; 10; 11; 12; 13; 14; 15; 16; 17; 18; 19; 20; 21; 22; 23; 24; 25; 26; 27; 28; 29; and 30 GBq in a multidose injection vial.
One vial contains the activity of fludeoxyglucose (^{18}F) of 100 to 1500 MBq/ml at the time of calibration.

Manufacturer and Marketing Authorisation Holder

ÚJV Řež, a. s., Hlavní 130, 250 68 Husinec-Řež, Czech Republic
The full Summary of Product Characteristics for Fludeoxyglucose is available HERE.

Product Name
Fludeoxyglucose (18F) UJV

Marketing Authorisation Number

88/418/16-C

Pharmacotherapeutic Group

Diagnostic radiopharmaceuticals; tumour detection, other diagnostic radiopharmaceuticals; ATC code: V09IX04

Active Substance

Fludeoxyglucosum (18F) 100–1500 MBq/ml at the date and time of calibration. The activity per vial ranges from 500 MBq to 30,000 MBq at the date and time of calibration. Fluorine (^{18}F) has a half-life of 110 minutes.

Pharmaceutical Form

Clear, colourless or slightly yellow solution for injection, free of visible particles.

Indications

Fludeoxyglucose (^{18}F) is intended for diagnostic use only; it is indicated for use in conjunction with positron emission tomography (PET) in adults and in the paediatric population.

- **Oncology:** In patients undergoing oncological examinations of functions or diseases, where the diagnostic objective is imaging of increased glucose uptake in specific organs or tissues. For documented indications, see the full text of the Summary of Product Characteristics.
- **Cardiology:** Assessment of myocardial tissue viability.
- **Neurology:** Interictal glucose metabolism, localisation of epileptogenic foci.

- **Infectious or inflammatory diseases:** the diagnostic target is tissue or structures with an abnormal accumulation of activated white blood cells.

See the full Summary of Product Characteristics for detailed information on indications.

Method of Administration

The product is administered as a single intravenous injection.

Shelf Life

12 hours from the end of manufacture

Storage

This product does not require any special temperature storage conditions. Store in accordance with national regulations for the handling of radioactive materials.

Packaging

- Inner packaging: Multidose glass injection vial (10 ml or 20 ml), closed with a dark grey bromobutyl rubber stopper, an aluminium seal, and a sterile plastic seal.

- Outer packaging: Lead container type P30, HU GP-40 container, or other types of containers approved for the transport of radioactive substances. Protective transport container: sealed metal can (for the P-30 container), steel case (for the HU GP-40 container), or other containers according to their design.

Pack Size

One vial contains 0.5 to 20 ml of the product, corresponding to an activity of 500 to 30,000 MBq at the date and time of calibration. Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder

ÚJV Řež, a. s., Hlavní 130, 250 68 Husinec-Řež, Czech Republic
The full Summary of Product Characteristics for Fludeoxyglucose (18F) UJV is available HERE.

Product Name
Sodium Fluoride (^{18}F) UJV 100–1500 MBq/ml solution for injection

Marketing Authorisation Number

88/394/16-C

Pharmacotherapeutic Group

Diagnostic radiopharmaceuticals; tumour detection, other diagnostic radiopharmaceuticals; ATC code: V09IX06

Active Substance

One ml of solution for injection contains sodium fluoride (^{18}F) 100–1500 MBq at the date and time of calibration. The activity in the vial ranges from 0.5 to 30 GBq at the date and time of calibration. Fluorine (^{18}F) has a half-life of 110 minutes

Pharmaceutical Form

Clear, colourless solution for injection, practically free of particles

Indications

This product is intended for diagnostic use only; it is indicated for use with positron emission tomography (PET) for functional imaging in diseases where the objective is to detect abnormally altered osteogenic activity.
The documented indications specifically include:
- Detection and localisation of bone metastases in cancers in adults and children
- Assistance in evaluating back pain of unclear origin in adults when the results of conventional imaging methods are inconclusive
- Assistance in detecting the presence of bone lesions in children associated with suspected abuse

Method of Administration

The product must be administered by intravenous injection.

Shelf Life

10 hours from the end of manufacture

Storage

This product does not require any special temperature storage conditions. Store in sealed containers in accordance with the regulations on protection of health against ionising radiation.

Packaging:

- **Inner packaging:** Multidose injection vial (10 ml or 20 ml) made of Class I hydrolytic glass, closed with a rubber stopper and an aluminium seal.
- **Outer packaging:** Lead container of type P30, HU GP-40 container, or other types of containers approved for the transport of radioactive materials.

Pack Size

0.5; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5; 5.5; 6; 6.5; 7; 7.5; 8; 8.5; 9; 9.5; 10; 11; 12; 13; 14; 15; 16; 17; 18; 19; 20; 21; 22; 23; 24; 25; 26; 27; 28; 29; and 30 GBq in a multidose injection vial. One ml of the product contains an activity of 100 to 1500 MBq at the date and time of calibration.
Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder:

ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech Republic
The full Summary of Product Characteristics for Sodium Fluoride (18F) UJV is available HERE.

Product Name

Fluorocholine (18F) UJV 100–3000 MBq/ml solution for injection

Marketing Authorisation Number

88/001/18-C

Pharmacotherapeutic Group

Diagnostic radiopharmaceuticals; tumour detection; ATC Code: V09IX07

Active Substance

One ml of solution for injection contains 100–3000 MBq of fluorocholine (^{18}F) chloride at the date and time of calibration. Fluorine (^{18}F) has a half-life of 109.8 minutes.

Pharmaceutical Form

Clear, colourless solution for injection, free of particles

Indications

Fluorocholine (18F) UJV is a diagnostic radiopharmaceutical intended for the positron emission tomography (PET) method in adults in the following indications:

- **Prostate cancer**
  - Initial staging of prostate cancer in patients with intermediate and high risk
  - Localisation of a recurrence and metastases of prostate cancer
- **Localisation of parathyroid adenoma or hyperplasia** in suspected primary hyperparathyroidism
- **Hepatocellular carcinoma**
  - Localisation of lesions of well-differentiated hepatocellular carcinoma
  - As an adjunct to FDG PET; characterisation of liver nodules and/or staging of proven or highly suspected hepatocellular carcinoma, if the FDG PET method does not sufficiently conclusive, or if surgical treatment or transplantation is planned

Method of Administration
The product is administered as a single intravenous injection.

Shelf Life
12 hours from the end of manufacture

Storage
The product must be stored in sealed containers in accordance with the regulations on health protection against ionising radiation. Do not freeze.

Packaging
- **Inner packaging:** 10ml injection vial made of Class I hydrolytic glass, closed with a rubber stopper and an aluminium seal
- **Outer packaging:** Lead, tungsten, or uranium container

One vial contains 0.5 to 10 ml of the product, corresponding to an activity of 100 to 30,000 MBq at the date and time of calibration.

Pack Size

0.5; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5; 5.5; 6; 6.5; 7; 7.5; 8; 8.5; 9; 9.5; 10; 11; 12; 13; 14; 15; 16; 17; 18; 19; 20; 21; 22; 23; 24; 25; 26; 27; 28; 29; and 30 GBq in a multidose injection vial.
Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder
ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech Republic
The full Summary of Product Characteristics for Fluorocholine (18F) UJV is available HERE.

Product Name
Methionine (11C) methyl UJV 100–1500 MBq/ml solution for injection

Marketing Authorisation Number
88/137/18-C

Pharmacotherapeutic Group
Diagnostic radiopharmaceuticals; tumour detection; ATC Code: V09IX13

Active Substance
One millilitre contains methioninum ([11C]methyl) 100–1500 MBq at the date and time of calibration. Carbon (^{11}C) has a half-life of 20 minutes.

Pharmaceutical Form
Clear, colourless solution for injection, free of visible particles

Indications

^{11}C-methionine is a diagnostic radiopharmaceutical, primarily intended for the detection of gliomas using positron emission tomography (PET) in adults and the paediatric population.

Method of Administration

The activity of ^{11}C-methionine must be measured using a calibrator just before injection.
The injection must be strictly intravenous to prevent irradiation due to local extravasation and to avoid imaging artefacts.
One vial may be used for single or multiple applications.
Do not administer more than 5 ml.

Shelf Life

The shelf life is 2 hours from the end of manufacture. The expiry date is marked on both the inner and outer packaging (container). The product must not be used after the stated expiry date.

Storage

Store in closed containers, in accordance with regulations on health protection against ionising radiation.

Packaging

- **Inner packaging:** 10 ml injection vial made of Class I hydrolytic glass, closed with a rubber stopper and an aluminium seal.
- **Outer packaging:** Lead, tungsten, or uranium container with appropriate certification.

One vial contains 0.5 to 10 ml of the solution, corresponding to 500 to 15,000 MBq at the date and time of calibration.

Pack Size

0.5; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5; 5.5; 6; 6.5; 7; 7.5; 8; 8.5; 9; 9.5; 10; 11; 12; 13; 14; and 15 GBq in a multidose injection vial.
Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder

ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech Republic
The full Summary of Product Characteristics for Methionine (11C) methyl UJV is available HERE.

Product Name
Fluorodopa (18F) UJV 100–3000 MBq/ml solution for injection

Marketing Authorisation Number
88/349/22-C

Pharmacotherapeutic Group
Other diagnostic radiopharmaceuticals for tumour detection; ATC code: V09IX05

Active Substance
100–3000 MBq/ml of fluorodopa (18F) at the date and time of calibration; fluorine (^{18}F) has a half-life of 110 minutes.

Pharmaceutical Form
Clear, colourless solution for injection, free of visible particles

Indications
This medicinal product is intended for diagnostic use only; it is indicated for use with positron emission tomography (PET) in adults and the paediatric population.

- **Neurology**
- Indicated for the detection of the loss of functional dopaminergic neuronal terminals in the striatum.
- Diagnosis of Parkinson's disease and differentiation between essential tremor and Parkinsonian syndromes
- **Oncology**
- PET with Fluorodopa (18)F provides a functional approach to pathologies, organs, or tissues where the diagnostic target is increased intracellular transport and decarboxylation of the amino acid dihydroxyphenylalanine.
- **Psychiatry**
- Detection of striatal dopamine synthesis capacity for the differential diagnosis of schizophrenia and prediction of the suitability of antipsychotic treatment.

Method of Administration
Slow intravenous injection, over approximately 1 minute.

Shelf Life
10 hours from the end of manufacture

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

Packaging
- Inner packaging: 10 ml injection vial made of Class I hydrolytic glass, closed with a rubber stopper and an aluminium seal
- Outer packaging: Lead, tungsten, or uranium container approved for transport.
One vial contains 0.5 to 10 ml of the product, corresponding to an activity of 100 to 30,000 MBq at the date and time of calibration.

Pack Size

0.5; 1.0; 1.25; 1.5; 1.75; 2.0; 2.5; 3.0; 3.5; 4.0; 4.5; 5.0; 5.5; 6.0; 6.5; 7.0; 7.5; 8.0; 8.5; 9.0; 9.5; 10.0; 11.0; 12.0; 13.0; 14.0; 15.0; 16.0; 17.0; 18.0; 19.0; 20.0; 21.0; 22.0; 23.0; 24.0; 25.0; 26.0; 27.0; 28.0; 29.0; and 30.0 GBq
Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder:

ÚJV Řež, a. s., Hlavní 130, 250 68 Husinec-Řež, Czech Republic
The full Summary of Product Characteristics for Fluorodopa (18F) UJV is available HERE.