ÚJV Řež, a. s.
Division of Radiopharmaceuticals

The aim of the Radiopharmaceuticals Division is to produce medicinal products at the highest European level and to develop new products on the basis of modern technologies.

Products:

Fludeoxyglucosa

Name of product: Fludeoxyglucosa

Manufacturer and holder of the registration decision: ÚJV Řež, a. s.,
Hlavní 130, 250 68 Husinec-Řež, Czech Republic

Indication group: radiopharmaceuticals – radionuclid diagnostic agent

Registration No.: 88/320/01-C

Medicinal substance: Fludeoxyglucosum (^{18}F) 100 - 1500 MBq / ml

Indication: localisation of primary tumours and metastases of most malignant neoplasms, evaluation of biological behaviour of tumours, assessment of the extent of tumorous diseases, evaluation of the efficiency of antitumour treatment, prognostic estimate of diseases, detection of disease recurrence, location of the area in which the epileptogenic zone is present, examination of regional utilization of glucose in the brains of patients with neurologic disorders, diagnosis of degenerative brain damage, diagnosis of inflammations, localisation of the cause of febrile events, assessment of myocardial viability.

Manner of administration: single application of Fludeoxyglucosa in an intravenous injection.

Applicability: 8 hours from calibration date and hour.

Storing: in temperature up to 25°C.

Inner container: injection vial (10 ml or 20 ml) from glass of the 1st hydrolytic class, closed with a rubber stopper and a metal overseal.

Outer container: lead container.

Package sizes: 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; 30 GBq in injection vial for a repeated administration.

ÚJV Řež, a. s. I Nuclear Research Institute
Hlavní 130, Řež, 250 68 Husinec, Phone +420 266 173 441, E-mail: sales@ujv.cz
Division of Radiopharmaceuticals
Phone: +420 266 172 178, E-mail: radiopharm@ujv.cz
www.ujv.cz

Fludeoxyglucose (18F) UJV

Name of product: Fludeoxyglucose (18F) UJV

Manufacturer and holder of the registration decision: ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech Republic

Indication group: radiopharmaceuticals – radionuclide diagnostic agent

Registration No.:88/418/16-C

Medicinal substance: 1 ml contains Fludeoxyglucosum (^{18}F) 100 – 1500 MBq to calibration date and time. The activity in the bottle ranges from 500 MBq to 30 000 MBq to calibration date and time.

Indication: this agent is intended only for diagnostic purposes. Fludeoxyglucose (^{18}F) is used se in connection with positron emission tomography (PET) in adults and in paediatric population.

Oncology – diagnosis – characterisation of solitary pulmonary node, detection of tumours of unknown origin with symptoms e.g. cervical adenopathy, hepatic or bone metastases, characterisation of formations on the pancreas, identification of the stage – tumours in the area of the head and throat, including biopsy assistance, primary lung cancer, locally advanced breast cancer, esophagus cancer, pancreatic cancer, colorectal tumour especially in recurrence restaging, malignant melanoma, Breslow
>1,5 mm or metastasis into lymphatic nodes during the first diagnosis, observing the therapeutic response – malignant lymphoma, tumours in the area of the head and throat, detection if there are reasonable grounds of recurrence.

Cardiology – assessment myocardial viability in patients with serious disorders of the function of the left chamber who are supposed to undergo revascularisation if conventional imaging procedures fail.

Neurology – localisation of epileptogenic foci in pre-operation assessment of partial temporal epilepsy.

Infectious or inflammatory diseases, localisation of abnormal foci in etiologic diagnoses with fevers of unknown origin, infection diagnosis, detecting the spread of inflammation, therapy observation.

Manner of administration: single application of product in intravenous injection.

Applicability: 12 hours after production is completed.

Storing: this product has no special requirements for storage temperature.

Inner container: glass injection vial (10 ml or 20 ml) for repeated administration closed with a dark grey bromobutyl rubber stopper, an aluminium overseal and a sterile plastic cap.

Outer container: lead container of the type P30, HU GP-40 container, or other container types approved for transporting radioactive substances.

Package sizes: 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; 30 GBq in injection vial for repeated administration.

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Sodium Fluoride (18F) UJV

Name of product: Fluorid (^{18}F) sodný UJV

Manufacturer and holder of the registration decision: ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech Republic

Indication group: radiopharmaceuticals – radionuclide diagnostic agent

Registration No.: 88/394/16-C

Medicinal substance: 1 ml of the injection solution contains sodium fluoride (^{18}F) 100 – 1500 MBq to calibration date and time. The activity in the bottle ranges from 0.5 to 30 GBq to calibration date and time.

Indication: this product is intended for diagnostic purposes only – detecting and localizing bone metastases in cancer diseases in adults and children, further as assistance in evaluating back pain of unknown origin in adults if results of conventional imaging methods are ambiguous and in detecting the presence of bone lesions in children if there is a suspicion of misuse.

Manner of administration: single application of product in intravenous injection.

Applicability: 10 hours after production is completed.

Storing: this product has no special requirements for storage temperature.

Inner container: injection vial (10 ml or 20 ml) for repeated administration, from glass of 1st hydrolytic class closed with a rubber stopper and a metal overseal.

Outer container: lead container of the type P30, HU GP-40 container, or other container types approved for transporting radioactive substances.

Package sizes: 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; 30 GBq in injection vial for repeated sampling.

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Fluorocholine (18F) UJV

Name of product: Fluorocholine (18F) UJV 100-3000 MBq/ml solution for injection

Manufacturer and holder of the registration decision: ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech republic

Indication group: radiopharmaceuticals – radionuclide diagnostic agent

Registration No.: 88/001/18-C

Medicinal substance: 1 ml solution for injection contains 100 - 3000 MBq/ml N - ([18F]fluoromethyl)-2-hydroxy-N,N-dimethylethan-1-aminium (fluorocholine (18F)) to calibration date and time.

The activity in the bottle ranges from 500 MBq to 30 000 MBq to calibration date and time.

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

Prostate carcinoma
– initial staging of prostate cancer in medium and high-risk patients,
– localization of recurrence and metastases of prostate cancer.

Localization of adenoma or parathyroid hyperplasia when primary hyperparathyroidism is suspected.

Hepatocellular carcinoma
– localization of lesions of well-differentiated hepatocellular carcinoma,
– in addition to PET with FDG, liver nod characterization and / or staging of proven or highly probable hepatocellular carcinoma, if PET with FDG does not provide sufficient evidence or if surgical treatment or transplantation is planned.

Manner of administration: single application of product in intravenous injection.

Applicability: 12 hours after production is completed.

Storing: The product must be stored in sealed containers in accordance with the regulations on protection of health against ionizing radiation. Do not freeze.

Inner container: injection vial 10 ml from glass of the 1st hydrolytic class, closed with a rubber stopper and an aluminium overseal.

Outer container: lead, tungsten or uranium container.

Package sizes: 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; 30 GBq in injection vial for repeated sampling.

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Methionine (11C) methyl UJV

Name of product: **Methionine (11C) methyl UJV 100 – 1500 MBq/ml solution for injection**

Manufacturer and holder of the registration decision: ÚJV Řež, a. s., Hlavní 130, Řež, 250 68 Husinec, Czech republic

Dosage form: radiopharmaceutical – solution for injection

Registration No.: 88/137/18-C

Pharmacotherapeutic group: diagnostic radiopharmaceuticals; tumour detection; ATC Code: V09IX13

Active ingredient: methionine ([11C]methyl) 100 – 1500 MBq

Indication:
11C-methionine is a diagnostic radiopharmaceutical, intended primarily to detect gliomas using positron emission tomography (PET) in adult and paediatric population.This product is intended only for diagnostic purposes.

Method of administration:
11C-Methionine UJV is supplied in a vial for repeated sampling.
This is a product for single application by intravenous injection.
The activity of 11C-methionine must be measured using a calibrator just before injection.
The injection is administered strictly intravenously to prevent irradiation as a consequence of local extravasation and also artifacts during projection.

Mechanism of action:
Methionine is a naturally occurring amino acid. Labelled 11C-methionine is used in radiodiagnostic imaging methods using increased accumulation of methionine in tumor tissues with increased intake of methionine and increased protein synthesis for their visualisation.

Appearance: clear colorless solution, free of visible particles.

Half-life: Carbon-(11C) has a half-life of 20 minutes.

Shelf-life:

The applicability time is 2 hours from the end of production. The expiration is marked on the inner and outer packaging (container). The product must not be used after the expiry of the shelf-life.

Storage: The product must be stored in sealed packaging, in accordance with regulations on protection of health against ionizing radiation.

Type of packaging – inner: 10 ml injection vial made of glass of the 1st hydrolytic class, sealed with a rubber stopper and an aluminium overseal. **– outer:** lead, tungsten or uranium container.

Package sizes: 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; 5; 10; 11; 12; 13; 14; 15; 16; 17; 18; 19; 20; 21; 22; 23; 24; 25; 26; 27; 28; 29; 30 GBq in an injection vial for repeated sampling.

Not all package sizes may be available on the market.

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Radiopharmaceuticals Division

Services

Complete construction of PET Centers

Our long-term and unique experience in the area in question allows us to offer and provide especially these services for establishing new PET Centers:

- Consulting services in establishing pharmaceuticals manufacturing processes
- Creating complete project documentation (construction and technological)
- Choosing suitable suppliers
- Inspection and qualification reports, launching operation
- Obtaining necessary authorisations and certificates for operation
- Complex training system for operating PET equipment

Production of investigational medicinal products

- The division is a holder of all necessary authorisations and certificates
- The division has the required premises, technology and expert staff

Quality control

Established control processes of chemical and physical character in the GMP regime (good manufacturing practice) cover areas of products of PET radiopharmaceuticals, as well as other pharmaceutical material.

Distribution of pharmaceutical products

Regarding drug distribution, transport and sale in the Czech Republic, we are a holder of the Good Distribution Practice certificate, we are officially authorised for management of ionising radiation, and our monitored vehicles and drivers are subject to the ADR regulations (European Agreement concerning the International Carriage of Dangerous Goods by Road).

Qualified person's (QP) activities

We have a sufficient number of experienced qualified workers with a high level of expertise and education, who are able to supply pharmaceutical products for sale.

Certificates and authorizations

- Authorization to manufacture medicinal and investigational medicinal products
- Authorization for the wholesale distribution of medicinal products
- Certificate of the good manufacturing practice for the manufacturer – medicinal products for human use
- Certificate of the good manufacturing practice for the manufacturer – investigational medicinal products for human use
- Permit of the State Office for Nuclear Safety for the management of ionizing radiation sources
- ISO 9001, ISO 14001, ISO 45001

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