ÚJV Řez, a. s.

Radiopharmaceuticals Division

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 Řez, a. s., Hlavní 130, 250 68 Husinec-Řez, 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 1° 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
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 \(^{18}\text{F}\) 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 \(^{18}\text{F}\) 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 myocardic 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 centres 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
**Sodium Fluoride (18F) UJV**

**Name of product:** Fluorid (18F) sodný UJV

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

**Indication group:** radiopharmaceuticals – radionuclid diagnostic agent

**Registration No.:** 88/394/16-C

**Medicinal substance:** 1 ml of the injection solution contains sodium fluoride (18F) 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 localising 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
Fluorocholine (18F)

**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 – radionuclid 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**

Detection of bone metastases of prostate carcinoma in high-risk patients.

**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 a 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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Radiopharmaceuticals Division
Services

Complete construction of the PET Center
Our long-term and unique experience in the area in question enables us in establishing the PET Center to provide especially these services:
■ Consultancy in introducing pharmaceutical production
■ Creating complete project documentation (construction and technological)
■ Selecting suitable suppliers
■ Inspection report, putting into operation
■ Obtaining necessary authorisations and certificates for operation
■ Complex training system for operating the PET equipment

Production of investigational medicinal products
■ The division is a holder of all necessary authorisations and certificates
■ It has relevant premises, technology and trained staff

Quality control
The set 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
In terms of 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 authorisations
■ Authorisation to manufacture medicinal and investigational medicinal products
■ Authorisation 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 ionising radiation sources