

PACKAGE LEAFLET: INFORMATION FOR THE USER

MUAE.¹⁸F-PSMA-1007 vial containing solution for I.V. injection Administered intravenously.

Active ingredient:

¹⁸F-PSMA-1007: 250 MBq /1 mL

In each vial the ¹⁸F-PSMA-1007 activity varies from 250 MBq to 18,5 GBq on the calibration date and time.

Excipients:

Water for injection, ethanol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *Please strictly follow the instructions given in this leaflet. Do not ever use higher or lower dose than the the dosage prescribed for and recommended to you .*

In this leaflet:

1. What is ¹⁸F-PSMA-1007 and what it is used for?
2. Before ¹⁸F-PSMA-1007 is administered
3. How ¹⁸F-PSMA-1007 will be used?
4. Possible side effects
5. How to store ¹⁸F-PSMA-1007?

1. What is MUAE.¹⁸F-PSMA-1007 and what it is used for?

MUAE.¹⁸F-PSMA-1007 is a radioactive drug used only for diagnostic purposes (Radiopharmaceutical) and contains F-18 radioactive isotope (tracer) labelled with precursor peptide PSMA-1007. This drug is administered intravenously only to help the diagnosis of the malignant (cancer) cells present in prostate gland.

It is administered before scanning (PET/CT) and helps to see a part of the interior body with a special camera. This scanning helps your doctor to detect tumors with high expression in prostate cancer cells and low expression in benign prostatic tissue.

This scanning could help your doctor to understand the state of tumor cells in prostate gland and tissues.

This imaging guides biopsy, staging of primary tumor, localization of biochemical relapse, planning of radiotherapy, prediction and assessment of tumor response to systemic therapy.

Your doctor or nurse will inform you on which part of your body will be scanned.

¹⁸F-PSMA-1007 is provided in colorless glass vials, located in special protective shield.

2. Before ¹⁸F-PSMA-1007 is administered

¹⁸F-PSMA-1007 must never be used

- If you are allergic to the drug substance (hypersensitivity), ¹⁸F-PSMA-1007 should not be administered to you. If you have doubts, consult your doctor or nurse,
- If you any Chronic kidney diseases (CKD) or Kidney related disease your doctor should not administer this drug to you,
- If you are pregnant, ¹⁸F-PSMA-1007 should not be administered to you,
- If you are breast-feeding, ¹⁸F-PSMA-1007 should not be administered to you.

Take special care with ¹⁸F-PSMA-1007

If any of the following condition is valid for you, you should talk to your doctor or nurse;

- If you are or have been on radiotherapy or chemotherapy, the results of the scan performed with ¹⁸F-PSMA-1007 may be affected.
- If you have recently received chemotherapy, you should wait for at least 4-6 weeks before administering this drug in order to avoid obtaining wrong negative results.
- If you have renal failure, since being exposed to radiation more will be a matter, your doctor will carefully assess your disease.
- Please tell your doctor if you have diabetes. Before the scan, your blood glucose level should be measured.
- Please tell your doctor if you have an infection or inflammatory disease.
- If you doubt you might be pregnant, have a test before using the drug.

"Please consult your doctor if any of these warnings applies to you even in a period in the past"

Before administration of ¹⁸F-PSMA-1007 you should:

- drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study
- avoid all important physical activity
- have sufficient amount of rest before neurological scanning to be performed in a dark and quiet environment
- be fasting for at least 4 hours

Pregnancy

Ask your doctor or pharmacist before taking any medicine.

You must inform your doctor before the administration of ¹⁸F-PSMA-1007 if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

Do not use this drug during pregnancy.

Ask your doctor or pharmacist before using this medicine if you are pregnant or might be pregnant.

Breast-feeding

Ask your doctor or pharmacist before taking any medicine.

Do not use this drug during breast-feeding.

Driving and using machines

It is considered unlikely that ¹⁸F-PSMA-1007 will affect your ability to drive or to use machines.

Important information about some of the ingredients of ¹⁸F-PSMA-1007

This medicinal product includes a small amount of ethanol (alcohol) [i.e. lower than 100 mg for every administration dose (maximum 3 mL)].

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How ¹⁸F-PSMA-1007 will be used?

RADIOPHARMACEUTICALS SHOULD BE ADMINISTERED ONLY BY NUCLEAR MEDICINE DOCTORS IN NUCLEAR MEDICINE CENTERS.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. ¹⁸F-PSMA-1007 will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will give required information to you, for the safe use of this product.

Instructions for appropriate administration and dose /administration frequency

The smallest quantity necessary to get the desired information will be used. Your doctor will determine the appropriate dose for you and administer that to you.

The quantity to be administered usually recommended for an adult ranges from 200 to 250 MBq (depending on the patient's body mass, the type of camera used for imaging and the acquisition mode). Megabecquerel (MBq) is the unit used to express radioactivity.

Use in children

In case of use in children, the quantity to be administered will be adapted to the child's weight.

Method and route of administration

¹⁸F-PSMA-1007 is administered intravenously.

- ¹⁸F-PSMA-1007 should always be administered in hospitals or clinics in the Nuclear Medicine Departments.
- One injection is sufficient to conduct the test.
- You may be asked to relax and stand still without reading or speaking. The reason for this is to decrease the tension in the muscles before the scan.
- Additionally, you may be asked to drink plenty of water and urinate before the start of the examination.
- Your doctor will inform you on the safe use of the drug.

Your doctor shall adjust the dose of the drug based on your disease and administer to you.

While the pictures are being taken, you will need to be completely at rest. You should not move or talk.

Duration of the procedure:

Your doctor will inform you about the usual duration of the procedure.

¹⁸F-PSMA-1007 is administered as a single injection in a vein, 45-60 minutes before the imaging acquisition takes place. The imaging acquisition with the camera, lasts 30 to 60 minutes.

Important information about ¹⁸F-PSMA-1007

You will be exposed to radioactivity when **¹⁸F-PSMA-1007** is administered.

- Your doctor will consider any potential risks and benefits for you before administering the drug.
- You will be recommended to urinate as frequently as possible after **¹⁸F-PSMA-1007** is administered. Thus, radioactivity will be excreted from your body.
- Your doctor will recommend you to avoid close contact with young children and pregnant women for the first 12 hours following the administration of **¹⁸F-PSMA-1007**

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you think that the effect of ¹⁸F-PSMA-1007 is too high or low, please ask your doctor or pharmacist.

If more ¹⁸F-PSMA-1007 is given to you than necessary

An overdose is unlikely because you will only receive a single dose of **¹⁸F-PSMA-1007** is administered as a single dose in a hospital or clinic by a Nuclear Medicine Doctor. If you have any concern regarding use of **¹⁸F-PSMA-1007**, you should talk with your doctor.

In this case, your doctor will recommend you to consume plenty of liquids and urinate frequently to speed up the excretion of the drug from the body.

If you forget to use ¹⁸F-PSMA-1007

This case is not applicable, since **¹⁸F-PSMA-1007** is administered by a doctor for diagnostic purposes.

If you stop using ¹⁸F-PSMA-1007

Please tell your doctor, if you observe any effect following the administration.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help to provide more information on the safety of this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store ¹⁸F-PSMA-1007?

It is not going to be necessary for you to store this medicine. This product should be kept under provision of the qualified persons, in appropriate places and conditions, according to relevant local regulations for radioactive materials.

¹⁸F-PSMA-1007 should be kept in hospitals and Nuclear Medicinal centers in a lead shielded container in room temperature below 30 °C.

It should be used within 14 hours as of the date and time of the manufacture.

Before use, vial should be controlled visually. It should be checked whether solution is clear and it contains particulate matter. When solution is not clear, it should not be used.

The product should not be used after expiry date.

Do not use ¹⁸F-PSMA-1007 after the expiry date which is stated on the packaging.

The hospital staff should ensure the product is stored accordingly. Also, they should ensure the product wastes are treated suitably and are not used after the shelf life specified on the label.

Manufacturer:

¹⁸F-PSMA-1007 is manufactured in Monrol UAE L.L.C located in Al-Qusais industrial area -1 Dubai P.O. Box 234373.

Information regarding these manufacturing sites are given below. Traceability of the batches is provided via Batch number mentioned on data-sheet shipped along with the drug.

For example; **P972201001**

Where;

P: Product code (P for **¹⁸F-PSMA-1007**)

97: Facility code of the manufacturing site i.e. Dubai:97

22: Last two numbers of year of manufacture

01: Month of manufacture

001: Batch number for that year

Manufacturer Address and contact details:

THIS IS A MEDICAMENT	
Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.	
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.	
-	The doctor and the pharmacist are experts in medicines, their benefits and risks.
-	Do not by yourself interrupt the period of treatment prescribed.
-	Do not repeat the same prescription without consulting your doctor.
-	Keep all medicaments out of reach of children.
Council of Arab Health Ministers Union of Arab Pharmacists	

Manufacturer and Marketing Authorization Holder



MONROL UAE LLC

Al Qusais Ind 1, P.O Box : 234373, Dubai, UAE

Phone: +971 (04) 257 81 03 Ext: 201, Fax: +971 (04) 257 81 04

Email: infouae@monrol.com, Website: www.monrol.com

Made in United Arab Emirates

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