MOLTEK FDG

I.V. Injectable Solution

PACKAGE LEAFLET: İNFORMATİON FOR THE USE

- **Active ingredient:** 45 mCi/ml Fluorodeoxyglucose (1650 MBq/mL ^{18}F) on the calibration date and time (t0 + 2 hours).
- **Excipients:** Ethanol and water for injection

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.
- İf you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others.
- Tell your doctor that you're using this medicine during the using, If you should go to the hospital or visit a doctor Please strictly follow the instructions given in this leaflet.
- Do not ever use higher or lower dose than the dosage prescribed for and recommended to you.

In this leaflet:

1. WHAT İS MOLTEK FDG AND WHAT İT İS USED FOR?

MOLTEK FDG is a radiopharmaceutical drug used for diagnostic purposes and contains a drug (18F) Florodeoksiglukoz. These medicine emit radiotion which are detected only with camera and invisible .After scanning, all images processes and used for diagnostic purposes.

MOLTEK FDG used for only diagnostic purposes.(for determine cause of the disease).
The Following case, you should take:

- **Oncology**: In patients with suspected or diagnosed cancer; differential diagnosis of benign/malign lesions during oncological diagnostic process, cancer staging, follow up of therapeutic response and restaging, early detection of recurrent disease.
- **Cardiology**: Evaluation of myocardial viability in patients with cardiac insufficiency who are candidates for revascularisation or transplant when conventional imaging modalities are not contributive.
- **Neurology:** In epilepsy patients for the identification of epileptogenic foci before surgery and for differential diagnosis of Alzheimer's Disease.
- **Infection**: For identification of fever of unknown origin and foci of infection.

2. BEFORE MOLTEK FDG (18F) İS ADMİNİSTERED

MOLTEK FDG MUST NOT BE USED İF:

- You are allergic to 18F-FDG and/or other substances contained in the solution
- You are a diabetic and your diabetes is currently not equilibrated
- You are pregnant
- You are breastfeeding

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Location: Moldova

TAKE SPECIAL CARE WITH MOLTEK FDG İF

- You received radiotherapy during the last 2-4 months: make sure that you inform your doctor, nurse or technician.
- You have recently received chemotherapy: make sure that you inform your doctor, nurse of technician.
- You have renal failure: inform your doctor for necessary dose adjustments
- You have infections or inflammatory conditions, inform your doctor.
- You are a diabetic: your blood glucose levels have to be stabilized before injection. If the scan imaging is for cardiac reasons glucose loading is required. If you are a diabetic you will be administered an insulin injection in combination with the glucose load.
- Avoid strenuous physical activity before the injection and scan.
- Prior to the neurological scan you have to have a relaxation period in a darkened room and with less background noise.

Please consult your physician if these warnings apply to you even in a previous period.
This drug involves exposure to small amounts of radioactivity. Your doctor will consider a scan only when expected benefits of this procedure outweighs any potential risk. You can be sure that the level of exposure to radioactivity will be the lowest possible dose that will help obtain the expected result from the procedure.

MOLTEK FDG WİTH FOOD AND DRİNK
MOLTEK FDG injection can only be administered in patients who have been fasting for minimum 4 hours.
Beverages containing glucose SHOULD ALSO BE AVOIDED during this period.
Inform your doctor if you have consumed food or fluids other than water prior to the scan. You can drink water in the quantity recommended by your physician.

Pregnancy
Consult your doctor or pharmacist before using the drug.

When administered to pregnant women MOLTEK FDG may cause defects in the unborn infant. Use during pregnancy should be avoided.
If you have to be administered MOLTEK FDG injection during pregnancy as an absolute necessity please ask your doctor for information about potential risks to the infant.
Consult your doctor or pharmacist promptly if you become pregnant during your treatment.

Breastfeeding
Consult your doctor or pharmacist before using the drug.

MOLTEK FDG is excreted in human milk.
Avoid use during breastfeeding.
Avoid close contact with your infant to minimize radiation exposure.

Driving and using machines:
There is no data about the effects on the ability to drive and use machines. Follow the instructions of your physician.
Important information on some of the excipients found in MOLTEK FDG
MOLTEK FDG contains a small amount of (0.1-0.5% h/h) ethanol.

Using other medicines:
The following medicines may influence the imaging results:

- Corticosteroids (also known as steroids)
- Sodium valproate, carbamezapine, phenytoin, phenobarbital (drugs used for epilepsy treatment)
- Colony-stimulating factors (used for cancer treatment)
- Glucose and/or insulin

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 MOLTEK FDG (^{18}F) WİLL BE USED?

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

Instructions for appropriate use and dose/frequency of administration:
This medicine shall be administered by a nuclear medicine specialist. The quantity to be used shall be the smallest quantity necessary to obtain the image to get the desired clinical information.

Method and route of administration
MOLTEK FDG is generally administered intravenously.

After administration of MOLTEK FDG and during scanning:

- You will be asked to consume a lot of fluids after the injection and urinate prior to and/or after the scan.
- Images are generally taken 40-60 minutes after injection. This may be longer for certain patients. The physician will decide on when to start the scans after the injection.
- During the scan you are required to remain at rest without speaking.
- Avoid any close contact with children during the initial 12 hours following the injection to prevent radiation exposure.

Special populations:
Pediatric population:
The radioactivity to be administered to children is calculated according to body weight and adjusted by your doctor.

Geriatric population:
No special considerations.

Special considerations:
In patients with reduced kidney function, careful consideration of the indication is required since an increased radiation exposure is possible in these patients.
MOLTEK FDG is excreted through the kidneys. Thus there is no need for dose adjustment in patients with hepatic impairment

If you have been given more MOLTEK FDG that you should:
An overdose is unlikely because you will only receive MOLTEK FDG in pre-controlled doses under the supervision of your doctor. However, in the case of an overdose, your doctor will advise you to drink a lot of fluids to help remove the product from your body.

If you forget to use MOLTEK FDG:
Does not apply since this medicine will be administered under the supervision of a nuclear medicine specialist.

Complications expected to occur following termination of MOLTEK FDG treatment:
No complications are expected to occur following administration of Moltek FDG.

4. POSSIBLE side effects?

Like all medicines MOLTEK FDG may cause side effects on persons who are sensitive to its ingredients.
Possible side effects of MOLTEK FDG injection are due to radioactivity. Exposure to radiation is linked with cancer induction or a potential for development of hereditary defects. After administration of the highest recommended dose of MOLTEK FDG radioactivity you will be exposed to is 4 times the radioactivity level due to environmental factors during within a year. This quantity is very much lower than the dose that causes cancer or any hereditary defects.
If you get any side effects not listed in this leaflet inform your doctor or pharmacist.

5. How is MOLTEK FDG stored

Keep out of reach and sight of children and store in its original container.
You will not be asked to handle, take home or store this medicine. MOLTEK FDG is prepared and stored only by Nuclear Medicine Specialists at Nuclear Medicine Centers.
Use according to the date and hour of expiry.
Store at room temperature below 25°C and in a suitable place according to relevant regulations.

6. OTHER INFORMATION

What MOLTEK FDG looks like and contents of the pack

MOLTEK FDG is supplied in a colorless bottle fitted with a rubber stopper and aluminum flip-off cap in its special carrier and is presented with instructions of use.
The personel to administer the drug shall first check whether the drug is fit for use.
For any information about this medicinal product contact the Authorization Holder.

Marketing authorization holder:

MOLTEK Moleküler Teknoloji San. Tic. A.Ş.
Gebze Organize Sanayi Bölgesi (GOSB) Şahabettin Bilgisu Caddesi No: 611/1
41470, Gebze, Kocaeli

Manufacturer:

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