

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### **FDG BioM® Multidose Injection** FLUORODEOXYGLUCOSE (<sup>18</sup>F)

**Read all of this leaflet carefully before you receive this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- 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.

#### **In this leaflet:**

1. What Fluorodeoxyglucose (<sup>18</sup>F)-BioM® is and what it is used for.
2. Before you are given Fluorodeoxyglucose (<sup>18</sup>F)-BioM®.
3. How you will be given Fluorodeoxyglucose (<sup>18</sup>F)-BioM®.
4. Possible side effects.
5. How to store Fluorodeoxyglucose (<sup>18</sup>F)-BioM®.
6. Further information.

## 1. WHAT FLUORODEOXYGLUCOSE (<sup>18</sup>F)-BIOM® IS AND WHAT IT IS USED FOR.

This medicine is for diagnostic use only.

It can be used for a technique called "positron emission tomographic" (PET) scan. With this technique it is possible to visualise the activity of cells in your body. This medicine is used to investigate tumor tissue, the functioning of your heart or epilepsy in the brain.

This will give doctors more information about:

- What may be wrong with you, **or**
- How well your treatment has worked, **or**
- If your disease has come back.

## 2. BEFORE YOU ARE GIVEN FLUORODEOXYGLUCOSE (<sup>18</sup>F)-BIOM®

### **Do not use Fluorodeoxyglucose (<sup>18</sup>F)-BIOM®:**

- If you are allergic (hypersensitive) to fluorodeoxyglucose or any of the other ingredients of Fluorodeoxyglucose (<sup>18</sup>F)-BIOM®,

### **Take special care with Fluorodeoxyglucose (<sup>18</sup>F)-BIOM®:**

- Your doctor will need to think carefully whether to give you Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® in some cases:
  - if you have diabetes (excess of sugar in blood)
  - if you have diabetes you may need to discuss with your doctor special arrangements for adjusting your blood sugar levels before your examination.
  - if you are under 18 years old
  - if you are pregnant
  - if you are breast feeding
  - if you have kidney problems
  - if you have recently had surgery, chemotherapy or radiotherapy
  - if you have an infection or an inflammatory disease e.g. arthritis (you may need to ask your doctor if you are not sure)
- You should also avoid strenuous physical activity before your examination.
- You may be told to avoid close contact with young children for 12 hours after the injection.

### **Using other medicines:**

All medicines that modify blood glucose (sugar) levels can influence the examination.

Examples are:

- Glucose containing products and insulin.
- Some medications to suppress inflammation (corticosteroids)

BioM®Colony-stimulating factors which may be given to prevent infections during cancer treatments can also affect the examination.

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

**Using Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® with food and drink:**

You will be asked to drink plenty of liquids, avoiding those containing sugars. You will be encouraged to pass water (urinate) after you have been given Fluorodeoxyglucose (<sup>18</sup>F) BIOM® because this removes 'radio-activity' from your body.

If the scan is made as part of the care for your disease, you should not eat for at least 4 hours before you are given Fluorodeoxyglucose (<sup>18</sup>F)-BIOM®.

**Pregnancy**

Please inform your doctor if you are pregnant or have missed a period. Your doctor will only use this product if he considers the benefit outweighs the risk.

**Breast-feeding**

Please inform your doctor if you are breastfeeding, he may want to postpone the procedure. If you do receive Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® during the period you are breastfeeding, you should not give milk to your baby during the first 12 hours after you have received the injection. The milk should be expressed and discarded. After 12 hours you can start breastfeeding again.

However, you may be told to avoid close contact with young children for 12 hours after the injection.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® has no known influence on your ability to drive and use machines.

**3. HOW YOU WILL BE GIVEN FLUORODEOXYGLUCOSE (<sup>18</sup>F)-BIOM® PREPARATION**

Always do exactly as your doctor has instructed you when preparing for the procedure.

In general you should drink plenty of fluids, avoiding those containing sugars. All physical activity should be avoided before the procedure.

You will be advised to lay down without speaking or reading.

A blood sample may be taken to test the glucose levels in your blood.

Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® will be given by intravenous injection. The dose is dependant on the procedure and equipment used in the hospital, generally for adults 100 to 400 MBq is given.

For children a lower dose will be calculated.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® can cause side effects, although not everybody gets them.

No side effects have been reported so far for Fluorodeoxyglucose (<sup>18</sup>F)-BIOM®.

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If you notice any side effects, please tell your doctor or pharmacist.

## 5. HOW TO STORE FLUORODEOXYGLUCOSE (<sup>18</sup>F)-BIOM®

The product label includes the appropriate storage conditions and the expiry date for the product.

## 6. FURTHER INFORMATION

### **What Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® contains.**

- The active substance is fludeoxyglucose (<sup>18</sup>F).
- The other ingredients are: sodium chloride, water for injections.

### **What Fluorodeoxyglucose (<sup>18</sup>F)-BIOM® looks like and contents of the pack.**

Fludeoxyglucose (<sup>18</sup>F)-BIOM® is a clear to slightly yellow solution in a vial, contained in a lead pot for protection against the radiation. When brought to you it will be in a shielded syringe.

**This leaflet was revised in 11/2017.**