PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
IASOdopa 0.3 GBq/mL, concentrate for solution for injection
6-fluoro-(^{18}F)-L-dihydroxyphenylalanine (or 6-fluoro-(^{18}F)-L-dopa)

Read all of this leaflet carefully before you will be administered 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 nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What IASOdopa is and what it is used for?

This medicine is a radiopharmaceutical product for diagnostic use only.

IASOdopa is used for diagnosis in Positron Emission Tomography (PET) examinations and is administered prior to such an examination.

The radioactive substance in IASOdopa (to show dopamine metabolism) is detected by PET and is shown as a picture.

Positron Emission Tomography is an imaging technology used in nuclear medicine that produces pictures of cross-sections of living organisms. It works with a minute amount of radioactive pharmaceutical to produce quantitative and precise images of specific metabolic processes in the body. This examination is carried out to help decide on how to treat the illness you are suffering from or you are suspected of suffering from.

2. What you need to know before IASOdopa is used?

IASOdopa must not be used :
- if you are allergic (hypersensitive) to the 6-fluoro-(^{18}F)-L-dopa or any of the other ingredients of IASOdopa or to any of the components of the medicinal product prepared before administration (see section 6),
- if you are pregnant.

Warnings and precautions :
Take special care with IASOdopa and inform your nuclear medicine doctor before being administered IASOdopa in the following cases :
- if you are pregnant or believe you may be pregnant,
- if you are breast-feeding,
- if you suffer from Parkinson's disease or are taking medicine for Parkinson's disease.

Before IASOdopa administration 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
- be fasting for at least 4 hours

Children and adolescents
Please talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and IASOdopa
Tell your nuclear medicine doctor who will supervise the procedure if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, since they may interfere with the interpretation of the images:
- Medicine for Parkinson's disease : if you are taking medicine for Parkinson's disease, you should stop taking this medicine at least 12 hours before your TEP examination
- Carbidopa (a medicine for Parkinson's disease)
- Haloperidol (an active substance used in psychotic symptoms, e.g. thought disorders or impaired consciousness)
- MAO (monoamine oxidase) inhibitors (medicine for depressions)
- Reserpine (active substance for lowering blood pressure)

IASOdopa with food and drink
You should be fasting for at least 4 hours before the administration of IASOdopa.
For the best quality image and so that radiation exposure of the bladder is reduced, it is, however, recommended that you drink plenty before and after the examination (water and unsweetened tea are permitted) and frequently empty your bladder.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of IASOdopa if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding. When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant
The use of IASOdopa is contraindicated in pregnant women.

If you are breast-feeding
If you are breast-feeding, breast milk may be drawn off before injection and stored for subsequent use. Breast-feeding should be stopped for at least 12 hours. Any milk produced during this period should be discarded.

Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
It is considered unlikely that IASOdopa will affect your ability to drive or to use machines.

IASOdopa contains sodium
Once prepared immediately before administration, this product may contain more than 1 mmol of sodium (23 mg). You should take this into account if you are on a low sodium diet.

3. How IASOdopa is used?

There are strict laws on the use, handling and disposal of radiopharmaceutical products. IASOdopa 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 take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of IASOdopa to be used in your case. It will be the smallest quantity necessary to get the desired information.

Adults
In oncology : the quantity to be administered usually recommended for an adult ranges from 2 to 4 MBq/kg (megabecquerel, the unit used to express radioactivity), depending on the patient's body mass, the type of camera used for imaging and the acquisition mode.
In neurology : this dose can be halved (1-2 MBq/kg body weight) for neurological examinations, i.e. when examining nervous system disorders for which an image of the entire body is not necessary.

Use in children and adolescents
There are few clinical data available on using this medicine for children and adolescents under 18.
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Administration of IASOdopa and conduct of the procedure
IASOdopa is administered by slow intravenous injection over a period of approximately one minute.
One injection is sufficient to conduct the test that your doctor needs.
After injection you will be offered a drink and asked to urinate immediately preceding the test.

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

After administration of IASOdopa, you should:
- avoid any close contact with young children and pregnant women for the 12 hours following the injection
- urinate frequently in order to eliminate the product from your body

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been administered more IASOdopa than you should
An overdose is almost impossible because you will receive a single dose of IASOdopa precisely controlled by the specialist physician supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. The elimination of the radioactive constituents should be increased as much as possible. You should drink as much as possible and frequently empty your bladder. It may become necessary to take diuretics.

Should you have any further question on the use of IASOdopa, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, IASOdopa can cause side effects, although not everybody gets them.
No serious adverse effects have been observed to date.
In rare cases, pain during the injection has been reported, which resolved within minutes without any specific measures.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. 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 provide more information on the safety of this medicine.

5. How IASOdopa is stored?

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.
IASOdopa must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information

What IASOdopa contains
- The active substance is 6-fluoro-(^{18}F)-L-dihydroxyphenylalanine (or 6-fluoro-(^{18}F)-L-dopa). 1 mL of concentrate for solution for injection contains 0.3 GBq 6-fluoro-(^{18}F)-L-dihydroxyphenylalanine (or 6-fluoro-(^{18}F)-L-dopa) at the date and time of calibration.
- The other ingredients are acetic acid and water for injections. The pH of the concentrate is between 2.3 and 3.0 and has to be adjusted prior to injection by addition of sodium bicarbonate.

What IASOdopa looks like and contents of the pack
IASOdopa is a clear and colourless or slightly yellow liquid.
The total activity of the vial at the date and time of calibration is between 0.15 GBq and 6 GBq.

Marketing Authorisation Holder

IASON GmbH
Feldkirchnerstraße 4
8054 Graz-Seiersberg
Austria

Manufacturer

ARGOS Zyklotron Betriebs GesmbH
St. Veiterstr. 47
9020 Klagenfurt
Austria

ARGOS Zyklotron Betriebs GesmbH
Seilerstaette 4
4020 Linz
Austria

Advanced Accelerator Applications SA
Technopole de l'Aube
14 rue Gustave Eiffel
10430 Rosières près Troyes
France

Advanced Accelerator Applications s.r.l
Via Ribes, 5
10010 Colleretto Giacosa (TO)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

France	IASOdopa 0.3 GBq/mL, solution à diluer injectable.
Austria	IASOdopa 0,3 GBq/mL - Konzentrat zur Herstellung einer Injektionslösung
Germany	IASOdopa 0,3 GBq/ml, Konzentrat zur Herstellung einer Injektionslösung
Italy	Fluorodopa IASON 0,3 GBq/mL, concentrato per soluzione iniettabile

This leaflet was last approved in
Detailed information on this medicine is available on the {member state medicines agency} web site: http://www.{ }.

The following information is intended for medical or healthcare professionals only:
The complete SmPC of IASOdopa is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC (SmPC should be included in the box)