

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

DOPACIS 90 MBq/mL, solution for injection

Fluorodopa (^{18}F)

Read all of this leaflet carefully before you will be administered this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your referring doctor or the specialist physician in Nuclear Medicine who will supervise the procedure.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your referring doctor or the specialist physician in Nuclear Medicine who has supervised the procedure.

In this leaflet:

1. **What Dopacis is and what it is used for**
2. **Before Dopacis is administered**
3. **How Dopacis will be used**
4. **Possible side effects**
5. **Further information**

1. WHAT DOPACIS IS AND WHAT IT IS USED FOR

This medicine is a radiopharmaceutical product for diagnostic use only.

Dopacis is a radioactive solution for injection of fluorodopa (^{18}F). Fluorine (^{18}F) is the radioactive element allowing the visualisation of the organs which binds fluorodopa (^{18}F). In fact, after injecting a small amount of Dopacis in a vein, the product can be located easily in your body by a camera which can visualise the radiation emitted by fluorine (^{18}F).

Dopacis is used :

- to determine the location or the progress of your illness, or
- to guide treatment decisions or to examine its effectiveness, according to the images of all or part of your body.

2. BEFORE DOPACIS IS ADMINISTERED

Dopacis must never be used

- if you are **allergic** (hypersensitive) to fluorodopa (^{18}F) or any of the other ingredients of Dopacis.
- if you are **pregnant**.

Take special care with Dopacis

Inform the specialist in Nuclear Medicine in the following cases :

- if you are **pregnant** or believe you **may be pregnant**,
- if you are **breast-feeding**,
- if you are **under 18 years old**.
- if you have any **kidney problem**.
- if you have had a **PET examination** within the last 5 days
- if you are taking any **antiParkinsonian treatment**
- if you are taking any **treatment with glucagon** (hyperglycaemic agent)

Taking other medicines

Please tell your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Please tell your physician if you are taking, or have been administered, any of the following medicines/substances, since they may interfere with your physician interpretation of the images:

- **Carbidopa, entacapone, nitecapone**
- **Glucagon**
- **Haloperidol**
- **Inhibitors of MAO (monoamine oxidase)**
- **Reserpine**

Using Dopacis with food and drink

You will be asked to **eat nothing for at least 4 hours** before the examination, however you will be encouraged to drink plenty of water.

Pregnancy and breast-feeding

Examinations in nuclear medicine may indeed involve a risk to the fetus. You must inform the specialist physician in Nuclear Medicine before the administration of Dopacis 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 physician or the specialist physician in Nuclear Medicine who will supervise the procedure.

If you are pregnant, Dopacis is contra-indicated in pregnancy.

If you are breast-feeding,

Resuming breast-feeding should be in agreement with the specialist in Nuclear Medicine who will supervise the procedure.

You must stop breast-feeding for 12 hours after the injection and the expressed breast milk must be discarded.

Please ask your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure before taking any medicines.

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Before Dopacis administration you should:

- be fasting for at least 4 hours, with unlimited amounts of water.
- stop any antiParkinsonian treatment **at least 12 hours before a neurological exam.**
- drink plenty of water and to be well hydrated before the start of the examination in order to urinate as often as possible during the first hours after the study.

After administration of Dopacis has been performed, you should:

- avoid any close contact with young children for the 12 hours following the injection.
- urinate frequently in order to eliminate the product from your body.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Dopacis will only be used in a hospital. 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.

Driving and using machines

It is considered unlikely that Dopacis will affect your ability to drive or to operate machinery.

Important information about some of the ingredients of Dopacis

This medicinal product contains less than 1 mmol sodium (23 mg) per injection, i.e. **essentially ‘sodium free’**.

3. HOW DOPACIS WILL BE USED

The specialist physician in Nuclear Medicine supervising the procedure will decide on the quantity of Dopacis to be used in your case. It will be the minimal quantity necessary to get the desired information. The quantity to be administered usually recommended for an adult is 4 MBq / kg body weight. The activity can be reduced by half in neurological indications where images of the entire body are not planned.

Use in children

In case of paediatric population, the quantity to be administered will be adapted to the child's body mass.

Administration of Dopacis and conduct of the procedure

Dopacis will be administered slowly, over a period of approximately one minute, into a vein in your arm. One injection is sufficient to provide your doctor with the information needed.

Duration of the procedure

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

If you have been administered more Dopacis than you should

An overdose is unlikely because you will only receive a single dose of Dopacis precisely controlled by the specialist physician supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the specialist physician in charge of the procedure may recommend that you drink abundantly in order to facilitate the elimination of Dopacis from your body. In fact this medicine is mainly eliminated by the kidneys, in urine.

Should you have any further question on the use of Dopacis, please ask your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dopacis can cause side effects, although not everybody gets them.

Burning sensation, application site pain, pain and application site warmth have been reported. Pain on injection site was reported to have dissipated spontaneously within a few minutes.

A case of 'carcinoid crisis' was reported: nausea, vomiting, diarrhea, rapid heart rate (tachycardia), hypotension, face and chest flushing.

This administered radiopharmaceutical will deliver low amount of ionising radiation with very low 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.

If you notice any side effects or if you notice any side effects not listed in this leaflet, please tell your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

5. FURTHER INFORMATION

What Dopacis contains

- **The active substance is** fluorodopa (^{18}F): 90 MBq / mL (at calibration date and time).
- **The other ingredients are :** acetic acid, sodium acetate, ascorbic acid, water for injections.

What Dopacis looks like and contents of the pack

You will not have to get or manipulate the package or bottle, what follows is only for your information.

The activity per vial ranges from 90 MBq to 900 MBq at the date and time of calibration.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

In Austria, Belgium, France, Ireland, Luxembourg, Malta ,The Netherlands, Portugal, Slovenia, Spain, United Kingdom :

CIS bio international

RN 306-Saclay

B.P. 32

F-91192 Gif-sur-Yvette Cedex

In Germany :

CIS bio GmbH

Alt-Moabit 91 d,

D-10559 Berlin

In Italy :

CIS bio S.p.A.

Piazza della Repubblica, 5

I-20121 Milano

Manufacturer

CIS bio international

F-33600 Pessac

CIS bio international

F-95200 Sarcelles

CIS bio international

F-54500 Vandœuvre-lès-Nancy

IBA Molecular Spain, S.A.

E-41092 Sevilla

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

Country	Product name
Austria	DOPACIS 90 MBq/mL, Injektionslösung
Belgium	Fluorodopa (¹⁸ F) CIS bio international 90 MBq/mL, solution injectable / oplossing voor injectie / Injektionslösung
France	DOPACIS 90 MBq/mL, solution injectable
Germany	DOPACIS 90 MBq/mL, Injektionslösung
Ireland	DOPACIS 90 MBq/mL, solution for injection
Italy	Fluorodopa (¹⁸ F) CIS BIO 90 MBq/mL, soluzione iniettabile
Luxembourg	DOPACIS 90 MBq/mL, solution injectable
Malta	DOPACIS 90 MBq/mL solution for injection
The Netherlands	DOPACIS 90 MBq/mL, oplossing voor injectie
Portugal	DOPACIS 90 MBq/mL, solução injectável
Slovenia	DOPACIS 90 MBq/mL, raztopina za injiciranje
Spain	DOPACIS 90 MBq/mL, solución inyectable
United Kingdom	DOPACIS 90 MBq/mL, solution for injection

This leaflet was last approved in.

Detailed information on this medicine is available on the web site of {MA/Agency}

The following information is intended for medical or healthcare professionals only:

The complete SmPC of Dopacis 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).