PACKAGE LEAFLET

Package leaflet: Information for the patient

Illuccix 25 micrograms kit for radiopharmaceutical preparation

gozetotide

Read all of this leaflet carefully before you are given 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 treating physician/nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Illuccix is and what it is used for

What Illuccix is
This medicine is a radiopharmaceutical product for diagnostic use only.

Illuccix contains a substance called gozetotide. Before it can be used, a pharmacist or your physician will mix the product with a radioactive substance called gallium-68 to make gallium (^{68}Ga) gozetotide. This procedure is called radiolabelling.

What Illuccix is used for
After radiolabelling with gallium-68, Illuccix is used in a medical imaging procedure called Positron Emission Tomography (PET) to detect specific types of cancer cells with a protein called prostate-specific membrane antigen (PSMA) in adults with prostate cancer. This is done:
- to find out whether prostate cancer has spread to lymph nodes and other tissues outside the prostate, before primary curative therapy (e.g. therapy involving surgical removal of the prostate, radiation therapy).
- when recurrence of prostate cancer is suspected in patients with increasing levels of serum prostate-specific antigen (PSA) who have received primary curative therapy.
- to find out whether patients with metastatic castration-resistant prostate cancer may be suitable for a specific therapy, called PSMA-targeted therapy.

How Illuccix works
When given to the patient, gallium (^{68}Ga) gozetotide binds to the cancer cells that have PSMA on their surface and makes them visible to your nuclear medicine doctor during the PET medical imaging procedure. This gives your doctor and nuclear medicine doctor valuable information about your disease.

The use of gallium (^{68}Ga) gozetotide does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical product outweighs the risk due to radiation exposure.

2. What you need to know before Illuccix is used

Illuccix must not be used:
- if you are allergic to gozetotide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your nuclear medicine doctor before you are given Illuccix if you have a kidney disease.

Before administration of Illuccix you should:
- drink plenty of water so that you remain hydrated and urinate immediately before the PET medical imaging procedure, and as often as possible during the first hours after the administration.

Children and adolescents
Talk to your nuclear medicine doctor if you are under 18 years old. Illuccix is not intended for use in children and adolescents aged under 18 years.

Other medicines and Illuccix
Tell your nuclear medicine doctor if you are taking, have recently taken or might take:
- any other medicines since they may interfere with the interpretation of the images.
- furosemide or any medicinal products used to increase urination.

Pregnancy and breast-feeding
Illuccix is not intended for use in women. All radiopharmaceuticals, including Illuccix, have the potential to cause harm to an unborn baby.

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

Illuccix contains sodium
This medicinal product contains up to 42 mg sodium (main component of cooking/table salt) per dose. This is equivalent to 2.1% of the WHO recommended maximum daily dietary intake of sodium for an adult.

3. How Illuccix is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Illuccix 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 Illuccix to be used in your case. It will be the smallest quantity necessary to get the desired information.
The quantity to be administered usually recommended for an adult ranges from 126 to 154 MBq (megabecquerel, the unit used to express radioactivity).

Administration of Illuccix and conduct of the procedure
After radiolabelling, gallium (^{68}Ga) gozetotide is administered as a slow injection into a vein. You will undergo a PET scan starting 50 to 100 minutes after you have received Illuccix.

A single injection is sufficient to conduct the test that your doctor needs.

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

After administration of Illuccix, you should:

- continue to drink plenty of water so that you remain hydrated and urinate as often as possible to eliminate the product from your body.
- avoid any close contact with young children and pregnant women for 2 hours after the injection.

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 given more Illuccix than you should
An overdose is unlikely because you will only receive a single dose of Illuccix precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive treatment, as necessary. You may be asked to drink and urinate frequently in order to eliminate the radiopharmaceutical product from your body.

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

4. Possible side effects

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

The following side effects can occur:

Rare (may affect up to 1 in 1,000 people):
- temporarily increased blood level of a digestive enzyme (amylase)
- constipation
- feeling weak
- bruising, warmth or rash at the injection site

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

Reporting of side effects
If you get any side effects, talk to your treating physician/nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How Illuccix 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 regulations on radioactive materials.

The following information is intended for the specialist only.
- Illuccix must not be used after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- before reconstitution, store in a refrigerator (2°C – 8°C).
- store in the original packaging in order to protect from light.
- after reconstitution and radiolabelling, store below 25°C and use within 2 hours. Do not freeze.

6. Contents of the pack and other information

What Illuccix contains

- the active substance is gozetotide. One vial contains 25 micrograms of gozetotide.
- the other ingredients are: D-mannose, hydrochloric acid, sodium acetate anhydrous and water for injections.

What Illuccix looks like and contents of the pack

Illuccix is a multidose kit for radiopharmaceutical preparation containing:
- a glass vial containing a white powder;
- a glass vial containing a clear and colourless solution;
- an empty glass vial used to radiolabel the final medication;
- label for radiolabelled product shielding.

The radioactive substance is not part of the kit and should be added during the preparation steps before injection.

Marketing Authorisation Holder and Manufacturer

TELIX INNOVATIONS S.A.
Rue de Hermée, 255
4040 Herstal
Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

Illuccix

Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden

This leaflet was last revised in 01/2025.

Other sources of information

Detailed information on this medicine is available on the website of Health Products Regulatory Authority (HPRA) (https://www.hpra.ie/)

The following information is intended for healthcare professionals only:

The complete SmPC of Illuccix is provided as a separate document in the product package, with the objective of providing healthcare professionals with additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.