

ILLUCCIX

Kit for Ga-68 Glu-urea-Lys(ahx)-hbed-CC radiopharmaceutical preparation

Consumer Medicine Information (CMI)

This leaflet provides important information about using ILLUCCIX. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about using ILLUCCIX.**

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1. What ILLUCCIX is used for?

ILLUCCIX is a multi-dose kit for the preparation of Ga-68 Ga-68 Glu-urea-Lys(ahx)-hbed-CC for intravenous use. There are 2 different kit configurations, each containing 3 vials. ILLUCCIX belongs to a group of medicines called radiopharmaceutical agents, which are all radioactive.

ILLUCCIX, after radiolabelling with Ga-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) imaging combined with Computerised Tomography (CT) scan in patients with prostate cancer:

- who are at risk of metastasis and who are suitable for any initial definitive therapy
- who have suspected recurrence based on elevated serum prostate specific antigen (PSA) level.
- for the selection of patients with metastatic prostate cancer in whom Lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated .

2. What should you know before you are given ILLUCCIX

Before you are given ILLUCCIX, your doctor will explain to you the procedure you are about to undergo, and the radioactive medicine you will be given. You must discuss any concerns you have with your doctor.

Warnings

You must tell your doctor if:

- you have kidney problems.
- you are allergic to any other medicines.

- you are allergic to any other substances such as foods, preservatives or dyes.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

ILLUCCIX is not indicated for use in females.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How ILLUCCIX is given?

How much is given

The quantity to be administered usually recommended for an adult ranges from 166.5 to 203.5MBq (megabecquerel, the unit used to express radioactivity).

Your doctor will decide how much you will be given.

How it is given

ILLUCCIX is administered by intravenous injection (bolus). ILLUCCIX should only be given by a doctor or a nurse.

5. When you are given ILLUCCIX

Things you should do

Avoid any close contact with young children and pregnant women for 2 hours after the injection.

Drink adequate amounts of water as advised by your doctor prior to administration of ILLUCCIX. During the first hour following administration, you should drink and void frequently to reduce radiation exposure.

Things you should not do

Do not take any other medicines unless advised by your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor if you notice anything else that may be making you feel unwell.

The following side effects of Gallium (68Ga) Ga-68 Glu-urea-Lys(ahx)-hbed-CC are common (may affect up to 1 in 100 people):

- feeling weak

Uncommon (may affect up to 1 in 1,000 people):

- nausea
- constipation
- diarrhoea
- vomiting

Rare (may affect up to 1 in 1,000 people):

- temporarily increased blood level of a digestive enzyme (amylase)
- pain or rash at the injection site, leakage of the medicine into surrounding tissue

This radiopharmaceutical will deliver a small amount of ionising radiation to your body for a short period of time. There is a very small risk of cancer or hereditary abnormalities developing in the future from this.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What ILLUCCIX looks like

ILLUCCIX is supplied as a sterile, multi-dose kit for the preparation of Ga-68 Ga-68 Glu-urea-Lys(ahx)-hbed-CC for intravenous use. There are 2 different kit configurations, each containing 3 vials.

What ILLUCCIX contains

ILLUCCIX Configuration "A":

- Vial 1 (Ga-68 Glu-urea-Lys(ahx)-hbed-CC Vial): contains 25 microgram Ga-68 Glu-urea-Lys(ahx)-hbed-CC and 10 microgram mannose and water for injections as a lyophilized powder in a sterile 10 mL vial with a blue flip-off cap.
- Vial 2 (Buffer Vial, Configuration A): contains 150 mg anhydrous sodium acetate, 0.077 mL hydrochloric acid and water for injections (2.5 mL volume) in a sterile 10 mL vial with a red flip off cap.
- Vial 3 (Sterile Vacuumed Vial): an evacuated sterile vial with white flip off cap used to collect Ga-68 chloride from generators or cyclotron

ILLUCCIX Configuration "B":

- Vial 1 (Ga-68 Glu-urea-Lys(ahx)-hbed-CC Vial): contains 25 micrograms Ga-68 Glu-urea-Lys(ahx)-hbed-CC and 10 micrograms mannose and water for injections as a lyophilized powder in a sterile 10 mL vial with a blue flip-off cap.
- Vial 2 (Buffer Vial, Configuration B): contains 150 mg anhydrous sodium acetate, 0.15 mL hydrochloric acid and water for injections (6.4 mL volume) in a sterile 10 mL vial with a green flip off cap.
- Vial 3 (Sterile Vacuumed Vial): an evacuated sterile vial with white flip off cap used to collect Ga-68 chloride from generator.

The radionuclide is not part of the kit. Before reconstitution and radiolabelling with Gallium 68, the contents of this kit are not radioactive.

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

AUST R 356332: ILLUCCIX Configuration A

AUST R 356333: ILLUCCIX Configuration B

Who distributes ILLUCCIX

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Sponsor:

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