

## Package leaflet: Information for the patient

### Gallium (<sup>67</sup>Ga) Citrate Injection 37 MBq/ml solution for injection Gallium (<sup>67</sup>Ga) citrate

**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 nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Gallium (<sup>67</sup>Ga) Citrate Injection is and what it is used for
2. What you need to know before Gallium (<sup>67</sup>Ga) Citrate Injection is used
3. How Gallium (<sup>67</sup>Ga) Citrate Injection is used
4. Possible side effects
5. How Gallium (<sup>67</sup>Ga) Citrate Injection is stored
6. Contents of the pack and other information

#### 1. What Gallium (<sup>67</sup>Ga) Citrate Injection is and what it is used for

This medicine is a radiopharmaceutical product for **diagnostic use** only.

Gallium (<sup>67</sup>Ga) Citrate Injection is used in combination with other imaging techniques to take photographs (scans) of:

- **various tumours** in adults and children over 1 month age
- **inflammatory lesions**, especially of the lung, in adults only.

Photographs (scans) can be made of the radioactive substance using a type of camera. This can be done from outside the body. This scan shows the distribution of radioactivity within the organ and the body. This also gives the doctor important information about how the organ works and how it is put together.

The use of Gallium (<sup>67</sup>Ga) Citrate Injection 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 outweighs the risk due to radiation.

#### 2. What you need to know before Gallium (<sup>67</sup>Ga) Citrate Injection is used

##### Gallium (<sup>67</sup>Ga) Citrate Injection must not be used:

- if you are allergic to gallium (<sup>67</sup>Ga) citrate or to any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or think you may be pregnant.
- if you are breast-feeding.
- in patients under 18 years old unless they have been diagnosed with cancer.
- in premature and newborn babies (up to 4 weeks old) due to the presence of benzyl alcohol.

If any of these apply to you, **talk to your nuclear medicine doctor.**

#### Warnings and precautions

Talk to your nuclear medicine doctor before you are given Gallium (<sup>67</sup>Ga) Citrate Injection:

- if you have a reduced kidney function.
- if you have a reduced liver function.

Your doctor will inform you if you need to take any special precautions after this medicine has been administered to you. Contact your nuclear medicine doctor if you have any questions.

### **Before administration of Gallium (<sup>67</sup>Ga) Citrate Injection 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.

### **Children and adolescents**

Particular care should be exercised in young child/adolescent due to the potential irradiation of the endplates in growing bone and haemopoietic tissues.

### **Other medicines and Gallium (<sup>67</sup>Ga) Citrate Injection**

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription since they may interfere with the interpretation of the images.

The following medicines may influence the gallium (<sup>67</sup>Ga) citrate examination:

- **medicines to treat mental disorders** with active substance names mostly ending in “azine” such as phenothiazines
- **certain medicines to treat cancer**
- **iron therapy**
- **medicines to treat depression:** amitriptyline, imipramine or similar substances,
- **medicines used to reduce activity in the immune responses**, including corticosteroids
- **contrast agents**
- **metoclopramide:** a medicine to treat nausea and vomiting
- **reserpine:** a medicine to treat high blood pressure
- **methyldopa:** a medicine to treat high blood pressure or heart problems
- **contraceptive pill:** an orally taken medicine to prevent pregnancy
- **stilboestrol:** a medicine to treat prostate cancer

### **Pregnancy and breast-feeding**

**You must inform the nuclear medicine doctor before the administration of Gallium (<sup>67</sup>Ga) Citrate Injection**, if you are pregnant or if there is a possibility you might be pregnant, if you have missed your period, if you are planning to have a baby 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**

This medicine must NOT be used if you are pregnant.

### **If you are breast-feeding**

This medicine must NOT be used if you are breast-feeding. Tell your doctor if you are breast-feeding as he/she may delay the scan until you are no longer breast-feeding.

He/she may also ask you to stop breast-feeding and to avoid close contact with your baby for 3 days following the injection.

### **Driving and using machines**

It is considered unlikely that Gallium (<sup>67</sup>Ga) Citrate Injection will affect your ability to drive or to use machines.

### **Gallium (<sup>67</sup>Ga) Citrate Injection contains sodium and benzyl alcohol.**

This medicine contains less than 1 mmol (23 mg) of sodium per dose, i.e. essentially sodium-free.

This medicine contains 9 mg/ml benzyl alcohol which may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) and death in young children (see contraindications).

### **3. How Gallium (<sup>67</sup>Ga) Citrate Injection is used**

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Gallium (<sup>67</sup>Ga) Citrate Injection 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 Gallium (<sup>67</sup>Ga) Citrate Injection 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 40-260 MBq (megabecquerel, the unit used to express radioactivity).

#### **Use in children and adolescents**

In children and adolescents, the quantity to be administered will be adapted to the child's weight.

#### **Administration of Gallium (<sup>67</sup>Ga) Citrate Injection and conduct of the procedure**

Gallium (<sup>67</sup>Ga) Citrate Injection is administered as an injection into a vein.

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

A laxative may also be recommended by your doctor for the detection of inflammatory bowel lesions. Your doctor will then take special care if you are an insuline dependent diabetic.

#### **Duration of the procedure**

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

#### **After administration of Gallium (<sup>67</sup>Ga) Citrate Injection, you should**

- urinate frequently in order to eliminate the product from your body.
- avoid any close contact with young children and pregnant women for 3 days following 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 Gallium (<sup>67</sup>Ga) Citrate Injection than you should**

An overdose is unlikely because you will only receive a single dose of Gallium (<sup>67</sup>Ga) Citrate Injection precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.

Should you have any further question on the use of Gallium (<sup>67</sup>Ga) Citrate Injection, 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.

Allergic reactions may occur with symptoms such as: warm sensation, generalised flushing, reddening of the skin, itching and/or itchy rash. The symptoms are generally mild and their frequency is not known (cannot be estimated from the available data).

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

### **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

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How Gallium (<sup>67</sup>Ga) Citrate Injection 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.

### **6. Contents of the pack and other information**

#### **What Gallium (<sup>67</sup>Ga) Citrate Injection contains**

- The active substance is gallium (<sup>67</sup>Ga) citrate.  
1 milliliter contains 37 MBq gallium (<sup>67</sup>Ga) citrate.
- The other excipients are sodium citrate dihydrate, benzyl alcohol, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

#### **What Gallium (<sup>67</sup>Ga) Citrate Injection looks like and contents of the pack**

This medicine is a clear, colourless radioactive solution.

The pack contains one multidose glass vial. Each vial is packaged in a lead shield container of an appropriate thickness.

Gallium (<sup>67</sup>Ga) Citrate Injection is supplied in a vial containing 2.2 ml (82 MBq), 3.3 ml (123 MBq), 5.5 ml (205 MBq) or 10 ml (370 MBq).

#### **Marketing Authorisation Holder and Manufacturer**

Curium Netherlands B.V.

Westerduinweg 3

1755 LE Petten

The Netherlands

**This leaflet was last revised in 11/2025.**

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

The complete Summary of Product Characteristics (SmPC) of Gallium (<sup>67</sup>Ga) Citrate Injection 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 of Gallium (<sup>67</sup>Ga) Citrate Injection.