

Gallium (Ga67) Citrate Injection

⁶⁷Ga as gallium citrate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Gallium (Ga67) Citrate is and what it is used for
2. Before you use Gallium (Ga67) Citrate
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1. What Gallium (Ga67) Citrate is and what it is used for

This medicine is for **diagnostic** use only.

Gallium (Ga67) Citrate is used through a scan to locate and examine:

- different **tumours** and
- specific **inflammations**, especially of the lung

This medicine contains a radioactive substance which when administered, collects in certain organs.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the organ and body. This also gives the doctor valuable information about the structure and function of that organ.

2. Before you use Gallium (Ga67) Citrate

Do not use Gallium (Ga67) Citrate

- if you are **allergic** (hypersensitive) to ⁶⁷Ga as gallium citrate or any of the other ingredients
- in **premature babies** and **neonates** (1 month)

Take special care with Gallium (Ga67) Citrate

This medicine does involve treatment with radioactivity. Your doctor will only give you this medicine if the benefit outweighs the risk.

Gallium (Ga67) Citrate is given by specialists, who will take responsibility for any necessary precautions.

Children

Lower doses are used for children according to their body weight.

Gallium (Ga67) Citrate **must not be used** in **premature babies** and **neonates** (1 month)

Gallium (Ga67) Citrate may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

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

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following **medicines** can **influence** the Gallium (Ga67) Citrate examination:

- **medicines to treat mental disorders** in the drug class "phenothiazines"
- certain **medicines to treat cancer, radiotherapy**
- **iron** as this may affect test results
- **amitriptyline, imipramine** or similar substances: medicines to treat depression
- **medicines used to reduce activity in the immune responses** including **cortisone**
- **X-ray contrast mediums**
- **metoclopramide**: a medicine to treat nausea and vomiting
- **reserpine**: a medicine to treat high blood pressure via the central nervous system
- **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

• Pregnancy

Tell your doctor if you are pregnant or think you could be. Your doctor will **only** administer Gallium (Ga67) Citrate during **pregnancy if it is absolutely necessary**, as it could harm the unborn child.

• Breast-feeding

Tell your doctor if you are breast-feeding as he may **delay treatment** until breast-feeding is finished. He may also ask you to **stop breast-feeding** until the radioactivity is no longer in your body.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Gallium (Ga67) Citrate is unlikely to impair the ability to drive and operate machinery.

Important information about some of the ingredients of Gallium (Ga67) Citrate

This medicine contains benzyl alcohol and must not be given to premature babies or neonates. May cause toxic reactions and allergic reactions in infants and children up to 3 years old.

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

3. How to use Gallium (Ga67) Citrate

Gallium (Ga67) Citrate will always be used in a hospital or similar setting. It will only be administered to you by qualified people trained to safe handle radioactive material.

Your doctor will decide the Gallium (Ga67) Citrate amount to be used.

The dose administered depends also on the disease. The lowest dose possible will be used to produce adequate images.

The usual dose is:

Approximate dose for **adults** and the elderly is:

- 37 - 260 MBq injected into a **vein**

MBq is the unit used to measure radioactivity, and defines the activity of a quantity of radioactive material.

Children under 18 years

Lower doses are used for children according to their body weight.

Gallium (Ga67) Citrate **must not be used** in **premature babies** and **neonates** (1 month).

Method of use

One injection is usually sufficient.

Scans are usually taken between 24 to 92 hours after injection, depending on the type of investigation.

If more Gallium (Ga67) Citrate is given than it should

It is unlikely that overdose will occur as this medicine is given under control by a doctor. However, if this happens you will receive appropriate treatment from your doctor.

Drinking as much as possible, such as water, will help remove the radioactive substance more quickly. Your doctor may additionally prescribe a laxative for you.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Gallium (Ga67) Citrate can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:

very rare, occurs in fewer than 1 per 10,000 users:

- allergic reactions
- flushes
- skin rash, itching
- swellings similar to after insect stings
- warm sensation

These symptoms may be signs of allergic reactions

Hospital staff will treat these reactions, if they occur.

frequency unknown, from the data available

- cancer or hereditary defects are linked to radiation exposure
However, the risk is very low as low doses are used in this investigation.

Reporting of side effects

If you get any side effects, talk to your Nuclear medicine doctor or nurse.

5. How to store Gallium (Ga67) Citrate

Keep out of the reach and sight of children.

Do not use Gallium (Ga67) Citrate after the expiry date stated on the label.

Hospital staff will ensure that the product is correctly stored; not above 25°C.

After opening the vial the solution must be used within 8 hours and stored in a refrigerator between 2-8°C.

If multi-dose use is intended, each aliquot should be removed under aseptic conditions, and within one working day.

Storage should take place in accordance with national regulations for radioactive materials.

Do not use Gallium (Ga67) Citrate if you notice that the outer packaging or glass vial are damaged

6. Further information

What Gallium (Ga67) Citrate contains

- The active substance is: ⁶⁷Ga as gallium citrate
One millilitre of Gallium (Ga67) Citrate contains 37 MBq.
- The other ingredients are: sodium citrate dihydrate, benzyl alcohol, sodium chloride, sodium hydroxide, hydrochloric acid, water for injections

What Gallium (Ga67) Citrate looks like and contents of the pack

Gallium (Ga67) Citrate is a clear, colorless solution. It is packaged in 10ml type 1 Ph.Eur glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

Gallium (Ga67) Citrate is supplied in one vial containing:

- 82 MBq (2.2 ml),
- 123 MBq (3.3 ml),
- 205 MBq (5.5 ml) or
- 370 MBq (10 ml).

Marketing Authorisation Holder and Manufacturer

Mallinckrodt Medical B.V.

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This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.
