How to order

Lantheus Gallium-67
(Gallium Citrate Ga 67 Injection)

Packaging:
- Lantheus Gallium-67 is supplied in a glass vial
- Concentration is 2 mCi per ml at calibration
- Available in 4 sizes:

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>mCi at day of Calibration</th>
<th>6 Day Pre Cal</th>
<th>5 Day Pre Cal</th>
<th>5 Day Pre Cal</th>
<th>3 Day Pre Cal</th>
<th>2 Day Pre Cal</th>
<th>1 Day Pre Cal</th>
<th>Day of Cal</th>
<th>1 Day Post Cal</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA6</td>
<td>6.6</td>
<td>24</td>
<td>19</td>
<td>15</td>
<td>12</td>
<td>10</td>
<td>7</td>
<td>6.6</td>
<td>5</td>
</tr>
<tr>
<td>GA8</td>
<td>8.8</td>
<td>32</td>
<td>25</td>
<td>21</td>
<td>17</td>
<td>13</td>
<td>11</td>
<td>8.8</td>
<td>7</td>
</tr>
<tr>
<td>GA12</td>
<td>13.2</td>
<td>47</td>
<td>38</td>
<td>31</td>
<td>25</td>
<td>20</td>
<td>16</td>
<td>13.2</td>
<td>10</td>
</tr>
<tr>
<td>GA18</td>
<td>19.8</td>
<td>71</td>
<td>57</td>
<td>46</td>
<td>37</td>
<td>30</td>
<td>24</td>
<td>19.8</td>
<td>16</td>
</tr>
</tbody>
</table>

Shipping:
- Orders placed each weekday by 4:30 PM (Eastern Time) will ship next day delivery
- Spot Orders - Availability based on weekly supply after standing orders are filled

Manufacturing:
- Manufactured on Wednesday
- Calibration is 12:00 noon (Eastern Time) following Thursday
- Expiry is 7 days post-calibration
- Physical half-life is 78.3 hours
- Holidays may result in manufacturing day schedule changes

Placing Orders:
- Recommended Ordering Method: Call Customer Service at 1-800-299-3431, Monday-Friday 7:30 AM – 4:30 PM (Eastern Time)
- Other Ordering Methods
  - Fax Orders/POs: 1-978-436-7501
  - Email: mics@lantheus.com
  - Online: https://ecommerce.lantheus.com
- Customer Service can assist you with establishing a weekly standing order if needed
- Priced by the vial
**GALLIUM CITRATE Ga 67 INJECTION**

**DESCRIPTION:** Gallium Citrate Ga 67 Injection is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. Each milliliter of the isotonic solution contains 74 MBq (2 mCi) of Gallium Ga 67 on the calibration date, as a complex formed from 9 ng Gallium Chloride Ga 67, 2 mg of sodium citrate, 8.8 mg sodium chloride, and 9 mg benzyl alcohol/mL, added as preservative. The pH is adjusted to between 4.5-6 with hydrochloric acid and/or sodium hydroxide solution. Gallium Ga 67, with a half-life of 78.3 hours, is cyclotron produced by the proton irradiation of enriched zinc oxide, and is essentially carrier-free and contains negligible concentrations of other radioisotopes.

The radionuclidic composition at calibration time is 99.8% Gallium Ga 67, ≤0.01% Gallium Ga 66 and ≤0.1% due to other radiocontaminants, each expressed as a percentage of total activity. The radionuclidic composition at expiration time is 99.89% Gallium Ga 67, essentially zero (0.0002%) Gallium Ga 66 and essentially zero of other radiocontaminants each expressed as a percentage of total activity.

The chemical structure for Gallium Citrate is shown below:

\[
\text{CH}_2\text{COO} \quad \text{HO-} \quad \text{C} \quad \text{COO-Ga} \quad \text{CH}_2\text{COO}
\]

**CLINICAL PHARMACOLOGY:** Carrier-free Gallium Citrate Ga 67 Injection has been found to concentrate in certain viable primary and metastatic tumors, as well as focal site of infection. The mechanism of concentration is unknown, but investigational studies have shown that Gallium Ga 67 accumulates in lysosomes and is bound to a soluble intracellular protein. It has been reported in the scientific literature that following intravenous injection, the highest tissue concentration of Gallium Ga 67 – other than tumors and sites of infection – is in the renal cortex. After the first day, the maximum concentration shifts to bone and lymph nodes, and after the first week, to liver and spleen. Gallium is excreted relatively slowly from the body. The average whole body retention is 65% after 7 days, with 25% having been excreted in the urine and 9% in the stools.

**INDICATIONS AND USAGE:** Gallium Citrate Ga 67 Injection may be useful in demonstrating the presence of the following malignancies: Hodgkin's disease, lymphomas and bronchogenic carcinoma. Positive Gallium Ga 67 uptake in the absence of prior symptoms warrant follow-up as an indication of a potential disease state.

Gallium Citrate Ga 67 Injection may be useful as an aid in detecting some acute inflammatory lesions.

**CONTRAINdications:** None known.

**WARNINGS:** Because of the benzyl alcohol content, caution should be used in administration to newborns, particularly infants born prematurely, and infants with impaired liver function.

The vial stopper contains dry natural rubber latex and may cause allergic reactions in providers or patients who are sensitive to latex.

**PRECAUTIONS:**

**General**

A thorough knowledge of the normal distribution of intravenously administered Gallium Citrate Ga 67 Injection is essential in order to accurately interpret pathologic studies.

The finding in an abnormal gallium concentration usually implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. Gallium Citrate Ga 67 Injection is intended for use as an adjunct in the diagnosis of certain neoplasms. Certain pathologic conditions may yield up to 40% false-negative gallium studies. Therefore, a negative study cannot be definitively interpreted as ruling out the presence of disease.

Gallium localization cannot differentiate between tumor and acute inflammation; and other diagnostic studies must be added to define the underlying pathology.

Gallium Citrate Ga 67 Injection, as well as any other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients consistent with proper patient management.

Radioisotopes should be used only by physicians who are qualified by training and experience in the safe use and handling of radioisotopes and whose expertise and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Gallium Citrate Ga 67 Injection affects fertility in males or females.

**Pregnancy**

Animal reproductive studies have not been conducted with Gallium Citrate Ga 67 Injection. It is also not known whether Gallium Citrate Ga 67 Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Gallium Citrate Ga 67 Injection should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radioisotopes, especially those electrolytes in nature, in a woman of childbearing capability, could be performed during the first few (approximately 10) days following the onset of menses.

**Nursing Mothers**

Gallium Citrate Ga 67 Injection is excreted in human milk during lactation; therefore, formula feedings should be substituted for breast feeding.

**Pediatric Use**

Safety and effectiveness in the pediatric population has not been established.

**Geriatric Use**

Clinical studies of Gallium Citrate Ga 67 Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

**ADVERSE REACTIONS:** Severe itching, erythema, and rash were observed in one patient of 300 studied.

The rare occurrence of hypersensitivity reactions or allergic reactions, skin rash, and nausea have been reported in association with Gallium Ga 67 use.

**DOSEAGE AND ADMINISTRATION:** The recommended adult (70 kg) dose of Gallium Citrate Ga 67 Injection is 74-185 MBq (2-5 mCi). Gallium Citrate Ga 67 Injection is intended for intravenous administration only.

Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended during the first week after injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 120 hours after injection.

The patient dose should be measured by a suitable radioactivity calibrator system immediately prior to administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Waterproof gloves should be worn during the handling procedures. With a shielded sterile syringe, aseptically withdraw the material for use. The expiration date of the drug is fourteen days after the date of manufacture.

**Radiation Dosimetry**

The estimated absorbed radiation doses from an intravenous injection of 185 MBq (5 mCi) of Gallium Citrate Ga 67 are shown in Table 4.

<table>
<thead>
<tr>
<th>Organ</th>
<th>Radiation Absorbed (mGy)</th>
<th>Absorbed Dose (μCi/MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Body</td>
<td>13.0</td>
<td>0.0016</td>
</tr>
<tr>
<td>Skeletal</td>
<td>22.0</td>
<td>0.0030</td>
</tr>
<tr>
<td>Liver</td>
<td>23.0</td>
<td>0.0031</td>
</tr>
<tr>
<td>Bone Marrow</td>
<td>29.0</td>
<td>0.0039</td>
</tr>
<tr>
<td>Spleen</td>
<td>26.5</td>
<td>0.0035</td>
</tr>
<tr>
<td>Kidney</td>
<td>20.5</td>
<td>0.0029</td>
</tr>
<tr>
<td>Ovaries</td>
<td>14.0</td>
<td>0.0021</td>
</tr>
<tr>
<td>Testes</td>
<td>12.0</td>
<td>0.0018</td>
</tr>
<tr>
<td>Gastrointestinal Tract</td>
<td>11.0</td>
<td>0.0016</td>
</tr>
<tr>
<td>Stomach</td>
<td>18.0</td>
<td>0.0025</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>28.0</td>
<td>0.0038</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>45.0</td>
<td>0.0061</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>45.0</td>
<td>0.0061</td>
</tr>
</tbody>
</table>

**HOW SUPPLIED:** Gallium Citrate Ga 67 Injection is supplied sterile and non-pyrogenic for intravenous use. Each mL contains 74 MBq (2 mCi) of Gallium Ga 67 on the calibration date, as a complex formed from 9 ng Gallium Chloride Ga 67, 2 mg of sodium citrate, 6.8 mg sodium chloride, and 9 mg benzyl alcohol/mL, as preservative. The pH is adjusted to between 4.5-6 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available in the following quantities of radioactivity: 244.2, 235.6, 488.4, and 732.6 MBq (6.6, 8.8, 13.2, and 19.8 mCi) of Gallium Citrate Ga 67 at calibration.

**NDC Number:** 11994-121

Store at controlled room temperature 20°-25°C (68°-77°F) [See USP].

The contents of the vials are radioactive and adequate shielding and handling precautions must be maintained.

This radioisotope is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 105 CMR 120.100 for the uses listed in 105 CMR 120.547 or 120.552 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.