**Gallium Citrate Ga 67 Injection**

**Rx only**

**DESCRIPTION**

Gallium Citrate Ga 67 Injection is supplied in a 10 milliliter vial as an isotonic, sterile, non-pyrogenic solution. Each milliliter of the isotonic solution contains 74 megabequerels (2 millicuries) of gallium 67 on the calibration date as a complex formed from 83 nanograms gallium chloride Ga 67, 1.9 milligrams of sodium citrate diphosphate, 7.8 milligrams of sodium chloride and 0.9 percent benzylic alcohol (v/v) as a preservative. The pH is adjusted to between 5.5 to 8.0 with hydrochloric acid and/or sodium hydroxide solution.

Gallium Ga-67, with a half-life of 78.26 hours, is cyclotron produced by the proton irradiation of enriched zinc. At the time of calibration the drug contains no more than 0.02% gallium Ga-66 and no more than 0.2% zinc Zn-65. The concentration of each radionuclidic impurity changes with time. At expiration, the drug contains no more than 0.001% gallium Ga-66 and no more than 1.0% zinc Zn-65. No carrier has been added.

Gallium citrate has the following chemical structure:

![Gallium Citrate Chemical Structure](image)

**Physical Characteristics**

Gallium Ga-67 with a physical half-life of 78.26 hours decays by electron capture to stable zinc Zn-65. Photons that are useful for imaging studies are listed in Table 1.

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean Percent Per Disintegration</th>
<th>Energy (MeV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>2.9</td>
<td>91.3</td>
</tr>
<tr>
<td>Gamma-3</td>
<td>35.7</td>
<td>93.3</td>
</tr>
<tr>
<td>Gamma-4</td>
<td>19.7</td>
<td>184.6</td>
</tr>
<tr>
<td>Gamma-5</td>
<td>2.2</td>
<td>209.0</td>
</tr>
<tr>
<td>Gamma-6</td>
<td>16.0</td>
<td>300.2</td>
</tr>
<tr>
<td>Gamma-7</td>
<td>4.5</td>
<td>393.5</td>
</tr>
</tbody>
</table>

**External Radiation**

The specific gamma ray constant for gallium Ga-67 is 1.6 R/mC-hr at 1 cm. The first half-value thickness of lead (Pb) is 0.066 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead is shown in Table 2. For example, the use of 1.2 cm of lead will decrease the radiation exposure by a factor of about 100.

<table>
<thead>
<tr>
<th>Shield Thickness (Pb), cm</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.066</td>
<td>0.5</td>
</tr>
<tr>
<td>0.41</td>
<td>10^-1</td>
</tr>
<tr>
<td>1.2</td>
<td>10^-2</td>
</tr>
<tr>
<td>2.5</td>
<td>10^-3</td>
</tr>
<tr>
<td>4.8</td>
<td>10^-4</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the time of calibration are shown in Table 3.

**INDICATIONS AND USAGE**

Gallium Citrate Ga 67 Injection may be useful as an aid in the detection and localization of tumors and sites of infection - is 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 Ga-67 is excreted relatively slowly from the body. The average whole body retention is 65 percent after seven days, with 26 percent having been excreted in the urine and 9 percent in the stools.

**CONTRAINDICATIONS**

None.

**WARNINGS**

None known.

**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 states. The finding of an abnormal gallium Ga-67 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 as well as focal areas of infection. Certain pathologic conditions may yield up to 40 percent false negative gallium Ga-67 studies. Therefore, a negative study cannot be definitely interpreted as ruling out the presence of disease.

Lymphocytic lymphoma frequently does not accumulate gallium Ga-67 sufficiently for unequivocal imaging and the use of gallium with this histologic type of lymphoma is not recommended at this time.

Gallium Ga-67 localization cannot differentiate between tumor and acute inflammation, and other diagnostic studies must be added to define the underlying pathology.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper management and to ensure minimum radiation exposure to occupational workers.

**CLINICAL PHARMACOLOGY**

Gallium Citrate Ga 67, with no carrier added, has been found to concentrate in certain viable primary and metastatic tumors as well as focal sites 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 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 Ga-67 is excreted relatively slowly from the body. The average whole body retention is 65 percent after seven days, with 26 percent having been excreted in the urine and 9 percent in the stools.

**DISPOSITION**

Gallium Citrate Ga 67 Injection may be useful to demonstrate the presence and extent of Hodgkin’s disease, lymphoma, and bronchogenic carcinoma. Positive gallium Ga-67 uptake in the absence of disease suggests metastatic or recurrent disease, lymphoma, and metastatic tumors as well as focal sites of infection. Negative gallium Ga-67 images may be obtained as early as 6 hours and as late as 120 hours after injection. Daily excretions and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

**INDICATIONS FOR USE**

Animal reproductive studies have not been conducted with Gallium Citrate Ga 67. It is also not known whether Gallium Citrate Ga 67 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 radiopharmaceuticals, especially those elective in nature of women of childbearing capability, should be performed during the first few (approximately ten) days following the onset of menses.

**Nursing Mothers**

This drug is known to be excreted in human milk during lactation, therefore, formula feedings should be substituted for breast feedings.

**Pediatric Use**

Safety and effectiveness in pediatric patients below the age of 18 have not been established.

**ADVERSE REACTIONS**

Rare occurrences of allergic reactions, skin rash and nausea have been reported in association with Gallium Citrate Ga 67 use.

**Dosage and Administration**

The recommended adult (70 kg) dose of Gallium Citrate Ga 67 Injection is 74 to 185 megabequerels (2 to 5 millicuries). Gallium Ga-67 injection is intended for intravenous administration only. Approximately 10 percent of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended from the day of 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 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 radioactive calibration system immediately prior to administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if contents are turbid.

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Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if contents are turbid.

**Instructions for the handling of Gallium Citrate Ga 67**

1. **Waterproof gloves should be used during the entire handling and administration procedure.**
2. **Using proper shielding, the vial containing the Gallium Citrate Ga 67 should be visually inspected to ensure that it is free of particulate matter and discoloration prior to use.**
3. **Maintain adequate shielding during the life of the product and use a sterile, shielded syringe for withdrawing and injecting the preparation.**

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Radiation Dosimetry

The estimated absorbed radiation doses\(^2\) from an intravenous injection of 185 megabecquerels (5 millicuries) of Gallium Citrate Ga 67 are shown in Table 4.

### Table 4. Absorbed Radiation Doses

<table>
<thead>
<tr>
<th>Tissue</th>
<th>mGy/185MBq</th>
<th>rads/5mCi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Body</td>
<td>13.0</td>
<td>1.30</td>
</tr>
<tr>
<td>Skeleton</td>
<td>22.0</td>
<td>2.20</td>
</tr>
<tr>
<td>Liver</td>
<td>23.0</td>
<td>2.30</td>
</tr>
<tr>
<td>Bone Marrow</td>
<td>29.0</td>
<td>2.90</td>
</tr>
<tr>
<td>Spleen</td>
<td>36.5</td>
<td>3.65</td>
</tr>
<tr>
<td>Kidney</td>
<td>20.5</td>
<td>2.05</td>
</tr>
<tr>
<td>Ovaries</td>
<td>14.0</td>
<td>1.40</td>
</tr>
<tr>
<td>Testes</td>
<td>12.0</td>
<td>1.20</td>
</tr>
<tr>
<td>Gastrointestinal Tract</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>11.0</td>
<td>1.10</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>18.0</td>
<td>1.80</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>28.0</td>
<td>2.80</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>45.0</td>
<td>4.50</td>
</tr>
</tbody>
</table>

### HOW SUPPLIED

Catalog Number 180.

Gallium Citrate Ga 67 Injection is supplied sterile and non-pyrogenic for intravenous use. Each milliliter contains 74 megabecquerels (2 millicuries) of gallium Ga-67 on the calibration date, as a complex formed from 8.3 nanograms gallium chloride Ga-67, 1.9 milligrams of sodium citrate dihydrate, 7.8 milligrams of sodium chloride, and 0.9 percent benzyl alcohol (v/v) as a preservative. The pH is adjusted to between 5.5 to 8.0 with hydrochloric acid and/or sodium hydroxide solution.

Gallium Citrate Ga 67 Injection is available in vials containing the following amounts on the calibration date.

- Catalog No. N180G0 222 megabecquerels (6 mCi)
- NDC 69945-180-06
- N180M0 444 megabecquerels (12 mCi)
- NDC 69945-180-12

### Storage and Handling

The contents of the vial are radioactive, and adequate shielding and handling precautions must be maintained. Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Storage and disposal of Gallium Citrate Ga 67 Injection should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

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Curium US LLC
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