

GALLIUM CITRATE GA-67- gallium citrate ga-67 injection, solution Curium US LLC

Gallium Citrate Ga 67 69945

Gallium Citrate Ga 67 Injection

Rx only

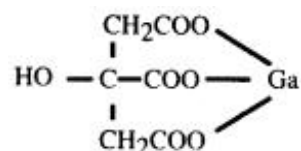
Diagnostic – For Intravenous Use

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 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 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:



Physical Characteristics

Gallium Ga-67 with a physical half-life of 78.26 hours¹ decays by electron capture to stable zinc Zn-67. Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-2	2.9	91.3
Gamma-3	35.7	93.3
Gamma-4	19.7	184.6
Gamma-5	2.2	209.0
Gamma-6	16.0	300.2
Gamma-7	4.5	393.5

¹ Kocher, D.C., Radioactive Decay Data Tables, Health and Safety Research Division, National Technical Information Service, DOE/TIC-11026, pg. 80, 1981.

External Radiation

The specific gamma ray constant for gallium Ga-67 is 1.6 R/mCi-hour 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 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb), cm	Coefficient of Attenuation
0.066	0.5
0.41	10 ⁻¹
1.2	10 ⁻²
2.5	10 ⁻³
4.8	10 ⁻⁴

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.

Table 3. Physical Decay Chart; Gallium Ga-67, Half-Life 78.26 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	72 (3d)	0.529
6	0.948	78	0.501
12	0.899	84	0.475
18	0.853	90	0.451
24 (1d)	0.809	96 (4d)	0.427
30	0.767	108	0.384
36	0.727	120 (5d)	0.345
42	0.689	132	0.311
48 (2d)	0.654	144 (6d)	0.279
54	0.620	156	0.251
60	0.588	168 (7d)	0.226
66	0.557		

* Calibration Time

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.

INDICATIONS AND USAGE

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 prior symptoms warrants 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.

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.

The vial contents are sterile and non-pyrogenic. It is essential that the user follow the

directions carefully and adhere to strict aseptic procedures.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience 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 or mutagenic potential or whether this drug affects fertility in males or females.

Pregnancy

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 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 megabecquerels (2 to 5 millicuries). Gallium Citrate 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 radioactivity 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.

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.

Radiation Dosimetry

The estimated absorbed radiation doses² from an intravenous injection of 185 megabecquerels (5 millicuries) of Gallium Citrate Ga 67 are shown in Table 4.

Table 4. Absorbed Radiation Doses

Tissue	mGy/ 185MBq	rads/ 5mCi
Whole Body	13.0	1.30
Skeleton	22.0	2.20
Liver	23.0	2.30
Bone Marrow	29.0	2.90
Spleen	26.5	2.65
Kidney	20.5	2.05
Ovaries	14.0	1.40
Testes	12.0	1.20
Gastrointestinal Tract		
Stomach	11.0	1.10
Small Intestine	18.0	1.80
Upper Large Intestine	28.0	2.80
Lower Large Intestine	45.0	4.50

² MIRD Dose Estimate Report No. 2, J. Nucl. Med. 14; 755-6 (1973).

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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Manufactured by:
Curium US LLC
Maryland Heights, MO 63043

Made in USA


A18010

CURIUM™

R07/2022

PRINCIPAL DISPLAY PANEL

Gallium Citrate Ga 67 Injection

Gallium Citrate Ga 67 Injection		Total Act.	MBq	Total Act.	MBq
R12/2018 A18010	DIAGNOSTIC Sterile, Non-Pyrogenic Solution For Intravenous Administration	(mCi)	(mCi)
	Store at Controlled Room Temperature 20° to 25°C (68° to 77°F).	As of 12 Noon CT		As of 12 Noon CT	
	Each milliliter contains 74 MBq (2 mCi) Gallium Citrate Ga 67 (essentially carrier free) at date and time of calibration, as a complex formed from 8.7 mg gallium chloride Ga 67, 1.9 mg sodium citrate dihydrate, 7.8 mg sodium chloride, and 0.9% (w/v) benzyl alcohol as a preservative. Sodium hydroxide or hydrochloric acid are added for pH adjustment. The pH is between 5.5 and 8.0.	Volume	ml	Volume	ml
	For information on dosage, administration and indications see package insert.	Conc.	MBq/mL	Conc.	MBq/mL
	Ready	(mCi/mL)	(mCi/mL)
	WARNING: Radioactive drugs must be handled only by qualified personnel in conformity with regulations of the U.S. Nuclear Regulatory Commission or state regulatory agencies where applicable. Bottle containing drug should be kept in this container or within heavier shield.	Sp. Act.	Essentially Carrier-Free	Sp. Act.	Essentially Carrier-Free
	Manufactured by: Curium US LLC Maryland Heights, MO 63043 Made in USA	Exp.		Exp.	
	CURIUM™	Lot		Lot	
					
					Gallium Citrate Ga 67 Injection DIAGNOSTIC
				CURIUM™	

GALLIUM CITRATE GA-67

gallium citrate ga-67 injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69945-180
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GALLIUM CHLORIDE GA-67 (UNII: A04B19O2B0) (GALLIUM CATION GA-67 - UNII:99T03J52W0)	GALLIUM CATION GA-67	2 mCi in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69945-180-06	1 in 1 CAN	02/21/2008	
1		3.3 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:69945-180-12	1 in 1 CAN	02/21/2008	
2		6.6 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018058	02/21/2008	

Labeler - Curium US LLC (079875617)