



Gallium [⁶⁷Ga] Citrate Injection BP

Description

The product is an injection containing radioactive Gallium [⁶⁷Ga] at an activity concentration of 100 MBq/mL at the calibration time and date. The product conforms to the British Pharmacopoeia for Gallium [⁶⁷Ga] Citrate Injection.

The dose sizes are made of 2 mL, 4 mL and 8 mL.

As supplied the product is sterile and contains 1% benzyl alcohol as a preservative. The product is designed for diagnostic use. Use by intravenous administration

Physical Characteristics of ⁶⁷Ga

Gallium-67 with a physical half life of 78.3 hours, decays by electron capture to stable zinc-67. Photons associated with this transition that are useful for detection and imaging studies are listed in Table 1.

Table 1: Principal Radiation Emission Data

Principal Radiation	Energy (KeV)*	Abundance
Gamma-2	37.0	93.3
Gamma-3	20.4	184.6
Gamma-5	16.0	300.2

Reference: Weber D A, Eckerman K F, Dillman L T and Ryman J C. MIRD. Radionuclide Data and Decay Schemes (1989)

Table 2: Physical Decay Chart

Time (hr)*	Factor	Time (hr)*	Factor
0	1.00	72	0.53
6	0.95	78	0.50
12	0.90	84	0.48
18	0.85	90	0.45
24	0.81	96	0.43
30	0.77	108	0.38
36	0.73	120	0.35
42	0.69	132	0.31
48	0.65	144	0.28
54	0.62	156	0.25
60	0.59	168	0.23
66	0.563		

External Radiation

The specific gamma ray constant for ⁶⁷Ga is 0.21 mGy per MBq-h at 1 cm. The first half value thickness of lead (Pb) for ⁶⁷Ga is 0.066 cm. Attenuation by lead is given in the following table.

Table 3: Radiation Attenuation by Lead Shielding

Shield Thickness mm Pb	Coefficient of Attenuation
0.066	0.5
0.41	0.1
1.2	0.01
2.5	0.001
4.8	0.0001

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Pharmacology

Upon intravenous injection, Gallium [⁶⁷Ga] Citrate concentrates in certain viable primary and metastatic tumours as well as focal sites of infection. The mechanism of concentration is unknown but investigations have shown that Gallium [⁶⁷Ga] accumulates in lysosomes and is bound to a soluble intracellular protein. It has been reported in scientific literature that following intravenous injection, the highest tissue concentration of Gallium [⁶⁷Ga] other than tumours 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 the liver and spleen. Gallium [⁶⁷Ga] excreted relatively slowly from the body. The average body retention is 65% after 7 days, with 26% having been excreted in the urine and 9% in the stools.

Indications and Usage

Gallium (⁶⁷Ga) Citrate Injection BP may be useful in demonstrating the presence and extent of Hodgkin's Disease, lymphomas and bronchogenic carcinoma. Positive uptake in the absence of prior symptoms may indicate a potential disease state. Gallium [⁶⁷Ga] may also be useful as an aid in detecting some acute inflammatory lesions.

Contraindications

None known.

Precautions

General

Radiopharmaceuticals should only be administered by medical practitioners who are qualified and licensed to handle radioisotopes.

A thorough knowledge of the normal distribution of intravenously administered Gallium [⁶⁷Ga] Citrate Injection BP is essential to accurately interpret pathological states. The finding of an abnormal Gallium-67

concentration normally implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. The product is also intended for use as an adjunct in the diagnosis of certain neoplasms, as well as focal areas of infection. Certain pathological conditions may yield up to 40% false negative Gallium [⁶⁷Ga] studies. A negative study can therefore not be definitely interpreted as indicating the absence of disease.

Gallium [⁶⁷Ga] Citrate Injection BP is not recommended for imaging lymphocytic lymphoma. This type of lymphoma frequently does not accumulate sufficient Gallium [⁶⁷Ga] to allow unequivocal imaging.

Gallium [⁶⁷Ga] localisation cannot differentiate between tumor and acute inflammation and other diagnostic studies must be undertaken to define the underlying pathology.

Dose Handling

Radiation exposure to clinical personnel must be minimised. Care and appropriate safety measures should always be used. The radioactivity of the dose should be checked with a suitable instrument immediately prior to administration.

Patient Care

Care should be taken to minimise unwanted radiation exposure to patients, consistent with proper patient management.

Pregnancy

It is not known if Gallium [⁶⁷Ga] Citrate can cause foetal harm when administered to a pregnant woman. Gallium [⁶⁷Ga] Citrate should only be given to a pregnant woman if in the judgement of the treating physician the expected benefits outweigh the potential hazards.

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Use during Lactation

Gallium [⁶⁷Ga] is excreted in human milk. It is recommended if not preferable for nursing mothers to completely cease feeding if possible, and if not, then breast feeding should be discontinued for at least 14 to 18 days. This would reduce the Effective Dose Equivalent (EDE) to the child to below 1mSv.
Reference: Europe J Nuc Med (1991) 18: 829-833 Nuc. Med Comm 10 15-27 (1989) J Nuc Med 1976 17: 1055-6

Paediatric Use

Safety and efficacy in children have not been established.

Note

Adequate long term studies have not been performed in animals to determine whether this drug affects fertility, or has teratogenic or mutagenic potential.

Warning

Although the product contains a preservative, a breached vial, for microbiological reasons, should be stored at 2-8°C for not more than 24 hours.

Disposal of all radioactive wastes should be carried out in accordance with the NH & MRC "Code of Practice for the Disposal of Radioactive Wastes by the User" 1985.

Adverse Reactions

The rare occurrence of allergic reactions, skin rash and nausea has been reported in association with Gallium-67 use.

Dosage and Administration

The suggested dose range for IV administration to be used in the average patient (70 kg) is 75-185 MBq. (400 MBq is the maximum recommended dose). Aseptic procedures should be used in preparing for injection.

The patient dose should be measured by a suitable radioactivity calibrator immediately before the administration.

Scanning post injection is optimal at about 48 hours. However, considerable biological variability may occur in individuals and acceptable images may be obtained as early as six hours and as late as 120 hours after injection.

Approximately 10% of the administered dose is excreted in the faeces 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 minimise the possibility of false positive studies.

Radiation Dosimetry

The estimated absorbed radiation doses to an average adult patient (70 kg) from Gallium [⁶⁷Ga] Citrate Injection are shown in table 4.

Table 4:

The Absorbed radiation doses following a 185 MBq injection of Gallium [⁶⁷Ga] Citrate Injection are estimated to be: mGy/185 MBq

Stomach	13.3
Small Intestine	10.9
Upper Large Intestine	22.2
Lower Large Intestine	37.0
Marrow	35.2
Kidneys	20.4
Bone	109.1
Liver	22.2
Spleen	27.8
Ovaries	15.2
Testes	10.5
Effective Dose Equivalent:	22 mSv/185 MBq 9 mSv/75 MBq

Reference: ICRP. Publication 53 (1987) Radiation dose to Patients from Radiopharmaceuticals

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Expiry

Expiry is 5 days after calibration.

Storage

Store below 25°C.

Presentation

The product is supplied in 10 mL serum vials.

The vial is contained in a 3 mm lead pot.

The pack sizes are:

100 MBq/1mL

200 MBq/2mL

300 MBq/3mL

400 MBq/4mL

800 MBq/8mL

TGA Approved Date

22 June 1993: Submitted to TGA.

27 July 1993: Approved by TGA.

15 Oct 1993: Resubmitted to TGA.

18 Oct 1993: Approved by TGA.

7 June 1994: Amended Table 3 and added

8mL pack size.

6 June 2001: Added 300 MBq / 3mL pack size.

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