CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219592Orig1s000

<u>LABELING</u>

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use GOZELLIX safely and effectively. See full prescribing information for GOZELLIX.

GOZELLIX™ (kit for the preparation of gallium Ga 68 gozetotide injection), for intravenous use
Initial U.S. Approval: 2020

----------INDICATIONS AND USAGE----------
GOZELLIX, after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:
- With suspected metastasis who are candidates for initial definitive therapy.
- With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. (1)

----------DOSAGE AND ADMINISTRATION----------
- Use appropriate aseptic technique and radiation safety handling measures in the manipulation and administration of Gallium Ga 68 Gozetotide Injection. (2.1)
- The recommended amount of radioactivity for adults is 111 MBq to 259 MBq (3 mCi to 7 mCi) as a bolus intravenous injection. (2.2)
- A diuretic expected to act within the uptake time period may be administered at the time of radiotracer injection. (2.2)
- Initiate imaging 50 minutes to 100 minutes after administration. The patient should void immediately prior to initiation of imaging. The scan should begin caudally and proceed cranially. (2.10)
- See full prescribing information for additional preparation, administration, imaging, and radiation dosimetry information. (2)

----------DOSAGE FORMS AND STRENGTHS----------
Kit for the preparation of Gallium Ga 68 Gozetotide Injection contains:
- Vial 1 (Gozetotide): 25 mcg gozetotide as a lyophilized powder in a multiple-dose vial
- Vial 2A (2.5 mL) or Vial 2B (6.4 mL) (Acetate Buffer): 150 mg of anhydrous sodium acetate as a sterile solution
  - Vial 2A in Configuration A for use with cyclotron-produced Ga 68 via GE FASTlab or ARTMS QIS, or EZAG generator
  - Vial 2B in Configuration B for use with IRE generator
- Ampule (Ascorbic Acid Stabilizer): 500 mg/2 mL (250 mg/mL) ascorbic acid (USP injection grade) as a sterile solution. (3)

After radiolabeling with Ga 68, Vial 1 contains up to 18,500 MBq (500 mCi) of Gallium Ga 68 Gozetotide Injection in 10 mL in a multiple-dose vial at calibration date and time.

----------CONTRAINDICATIONS----------
None (4)

----------WARNINGS AND PRECAUTIONS----------
- Risk for Misinterpretation: Gallium Ga 68 gozetotide uptake can be seen in a variety of tumor types and in non-malignant processes.Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended. (5.1)
- Radiation Risks: Ensure safe handling to protect patients and health care providers from unintentional radiation exposure. (2.1, 5.2)
- Hypersensitivity Reactions to Sulfites: Ascorbic Acid Stabilizer contains sodium metabisulfite, a sulfite that may cause life-threatening hypersensitivity reactions including anaphylaxis. (5.3)

----------ADVERSE REACTIONS----------
The most commonly reported adverse reactions include nausea, diarrhea, and dizziness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Telix Pharmaceuticals (US) Inc. at 1-844-455-8638 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 3/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Radiation Safety - Drug Handling
2.2 Recommended Dosage and Administration Instructions
2.3 Patient Preparation
2.4 General Instructions for Drug Preparation
2.5 Preparation with Cyclotron-Produced Ga 68 via GE FASTlab Solid or Liquid Target System
2.6 Preparation with Cyclotron-Produced Ga 68 via ARTMS QIS Solid Target System
2.7 Preparation with EZAG GalliaPharm Generator
2.8 Preparation with IRE ELiT Galli Eo Generator
2.9 Specifications and Quality Control
2.10 Image Acquisition
2.11 Image Interpretation
2.12 Radiation Dosimetry
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Risk for Misinterpretation
5.2 Radiation Risks
5.3 Hypersensitivity Reactions to Sulfites
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.4 Pediatric Use
8.5 Geriatric Use
10 OVERDOSAGE
11 DESCRIPTION
11.1 Drug Characteristics
11.2 Nuclear Physical Characteristics
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
14.1 Imaging Prior to Initial Definitive Therapy
14.2 Imaging Prior to Suspected Recurrence Therapy
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

GOZELLIX, after radiolabeling with Ga 68, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- With suspected metastasis who are candidates for initial definitive therapy.
- With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety - Drug Handling

After radiolabeling of GOZELLIX, the vial contains Gallium Ga 68 Gozetotide Injection. Handle Gallium Ga 68 Gozetotide Injection with appropriate safety measures to minimize radiation exposure *[see Warnings and Precautions (5.2)]*. Use waterproof gloves, effective radiation shielding, and other appropriate safety measures when preparing and handling Gallium Ga 68 Gozetotide Injection.

Radiopharmaceuticals should be used by or under the control of healthcare providers who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

2.2 Recommended Dosage and Administration Instructions

Recommended Dosage

In adults, the recommended amount of radioactivity to be administered for PET is 111 MBq to 259 MBq (3 mCi to 7 mCi) administered as an intravenous bolus injection.

Administration

- Use aseptic technique and radiation shielding when withdrawing and administering Gallium Ga 68 Gozetotide Injection.
- Calculate the necessary volume to administer based on calibration time and required dose.
- Inspect Gallium Ga 68 Gozetotide Injection visually for particulate matter and discoloration before administration. Only use solutions that are clear, colorless to slightly yellow, and without visible particles.
- Assay the final dose in a dose calibrator immediately before administration to the patient.
- After injection of Gallium Ga 68 Gozetotide Injection, administer an intravenous flush of sterile 0.9% Sodium Chloride Injection to ensure full delivery of the dose.
- Dispose of any unused drug in a safe manner in compliance with applicable regulations.
- Unless contraindicated, a diuretic expected to act within the uptake time period may be administered at the time of radiotracer injection to potentially decrease artifact from radiotracer accumulation in the urinary bladder and ureters.

2.3 Patient Preparation

Instruct patients to drink a sufficient amount of water to ensure adequate hydration prior to administration of Gallium Ga 68 Gozetotide Injection and to continue to drink and void frequently following administration to reduce radiation exposure, particularly during the first hour after administration *[see Warnings and Precautions (5.2)]*.

2.4 General Instructions for Drug Preparation

Ga 68 Sources and GOZELLIX Carton Configurations

GOZELLIX is supplied as a kit in two different carton configurations, A or B, for preparation of Gallium Ga 68 Gozetotide Injection with eluate from different Ga 68 sources. See Table 1 for GOZELLIX carton configurations to be used with different Ga 68 sources.

Table 1. Ga 68 Sources and GOZELLIX Carton Configuration

Ga 68 Source	GOZELLIX Carton Configuration to be Used
Cyclotron-produced via GE FASTlab	A
Cyclotron-produced via Alternative Radioisotope Technologies for Medical Science (ARTMS) QUANTM Irradiation System (QIS)	A
Eckert & Ziegler (EZAG) GalliaPharm Germanium 68/Gallium 68 (Ge 68/Ga 68) generator	A
IRE ELiT Galli Eo Ge 68/Ga 68 generator	B

The Ge 68/Ga 68 generators and cyclotron are not supplied with GOZELLIX. Follow the instructions for use provided by the Ge 68/Ga 68 generator or cyclotron manufacturer.

Components of GOZELLIX consist of Vial 1 (Gozetotide), Vial 2A or Vial 2B (Acetate Buffer), and an Ampule (Ascorbic Acid Stabilizer) *[see How Supplied/Storage and Handling (16)]*.

General Instructions

a. Follow aseptic techniques in all drug preparation and handling.
b. Use suitable shielding to reduce radiation exposure.
c. Wear waterproof gloves.
d. Place a "radioactive" label on Vial 1 (Gozetotide) with product name, lot number and date.
e. Remove the vial cap from Vial 1 (Gozetotide) and Vial 2A or Vial 2B (Acetate Buffer).
f. Swab the top of each vial and the outside of the ampule with alcohol to disinfect the surface and allow the top of each vial to dry.
g. Use the shortest possible needle for the transfer of the Gallium Ga 68 Chloride solution to minimize any potential metallic contamination. The needle should be clean and dilute acid resistant.
h. Use only plastic syringes for preparation and administration. **Do not** use syringes with rubber plungers.
i. Prior to use of any vial, confirm the correct vial by a visual check of the vial label.
j. Prepare the acetate buffer by adding 0.10 mL ascorbic acid stabilizer according to the instruction below before proceeding with the specific procedure depending on Ga 68 source.
k. Follow the specific preparation procedure dependent on Ga 68 source *[see Dosage and Administration (2.5, 2.6, 2.7, 2.8)]*.

Procedure for Addition of Ascorbic Acid Stabilizer to Acetate Buffer

1. Safely open the ascorbic acid stabilizer ampule.
2. Using an appropriately sized syringe (e.g., 0.5 mL syringe) fitted with a 5 micron 18 G x 1 1/2 inch sterile filter needle or equivalent, withdraw the solution of ascorbic acid, through the filter needle.

NOTE: The syringe must contain at least 0.10 mL of ascorbic acid stabilizer solution that can then be dispensed. The operator must account for the dead volume of the syringe and filter needle.

3. Remove the filter needle from the syringe and fit a sterile needle to the syringe containing the ascorbic acid.
4. Dispense 0.10 mL of the ascorbic acid stabilizer solution from the syringe into the acetate buffer vial (Vial 2A or Vial 2B).
5. After removal of the syringe from the vial, mix the contents by inverting the vial at least three times.

2.5 Preparation with Cyclotron-Produced Ga 68 via GE FASTlab Solid or Liquid Target System

Collection of Gallium Ga 68 Chloride Solution

After purification by the FASTlab, the Gallium Ga 68 Chloride solution is passed through a sterile filter and into the cassette product vial automatically by the FASTlab.

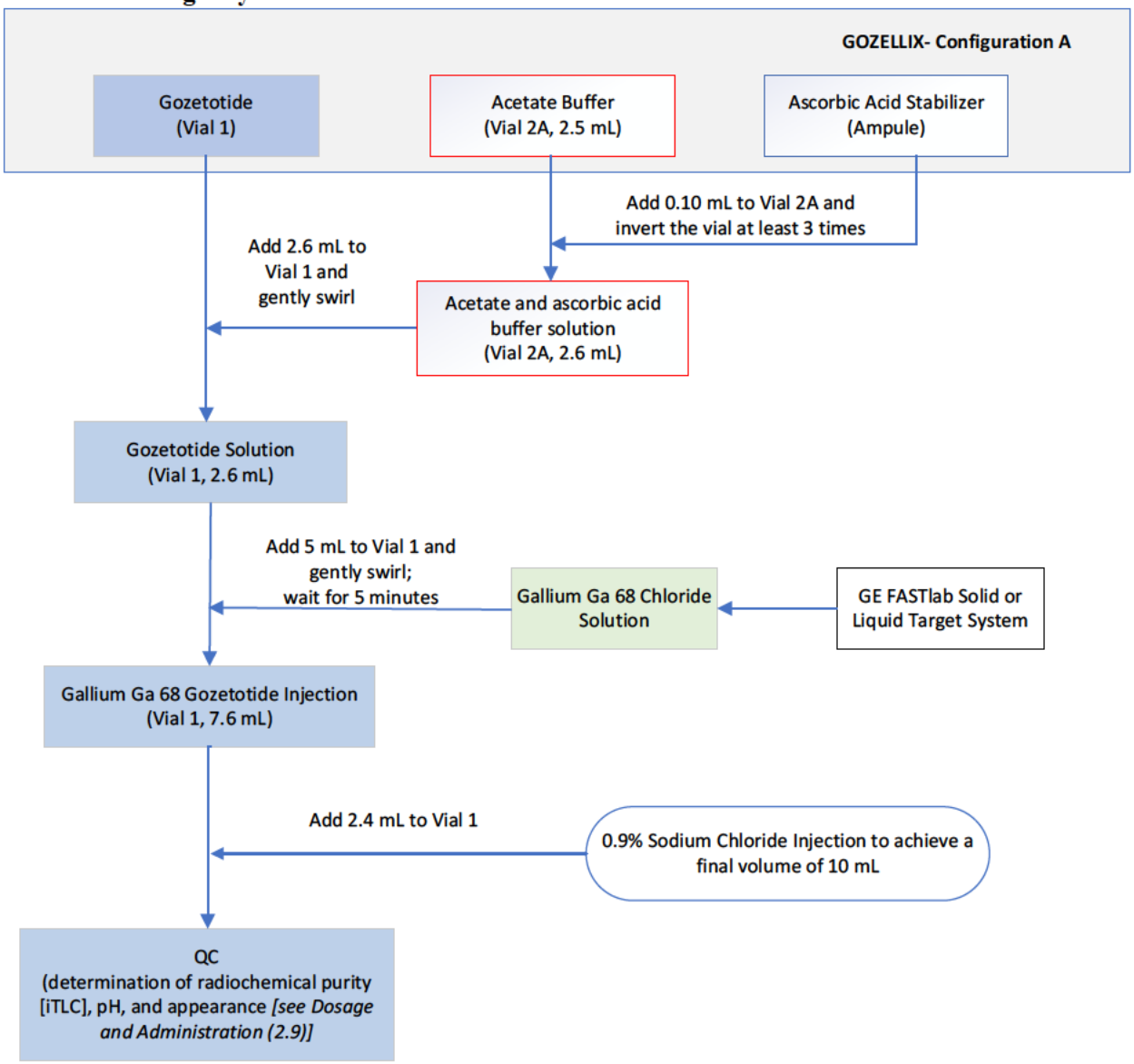
When Ga 68 is cyclotron-produced, test for Ga 66 and Ga 67 (with specification of ≤2% combined total) when a new lot of Zn 68 is introduced for manufacturing.

Radiolabeling Procedure

1. Use GOZELLIX "Configuration A" with cyclotron-produced Ga 68 via GE FASTlab Solid or Liquid Target System.
2. A schematic diagram for the preparation is provided in Figure 1.
3. Prepare the acetate buffer (Vial 2A) with ascorbic acid stabilizer as outlined in the procedure above *[see Dosage and Administration (2.4)]*.
4. Pierce Vial 1 (Gozetotide) with a sterile needle connected to a 0.2 micron sterile vented filter to maintain atmospheric pressure within the vial during the reconstitution process.
5. Insert a sterile syringe with a needle into Vial 2A containing the acetate and ascorbic acid buffer solution and draw up 2.6 mL of the solution.
6. Aseptically transfer the acetate and ascorbic acid buffer solution in the syringe into Vial 1 (Gozetotide).
7. Gently swirl Vial 1 to ensure the product is thoroughly dissolved in the buffer.
8. Aseptically transfer the 5 mL of Gallium Ga 68 Chloride solution made using the GE FASTlab Solid or Liquid Target System into Vial 1 (Gozetotide).
9. Remove the sterile vent filter.
10. Gently swirl Vial 1 to ensure the product is thoroughly mixed.
11. Wait for 5 minutes for radiolabeling to take place at room temperature (25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)).
12. Assay the whole vial containing the Gallium Ga 68 Gozetotide Injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration, and record the result.
13. Dilute the Gallium Ga 68 Gozetotide Injection with 2.4 mL of 0.9% Sodium Chloride Injection to a final volume of 10 mL.
14. Perform the quality control of Gallium Ga 68 Gozetotide Injection according to the recommended methods *[see Dosage and Administration (2.9)]*.
15. Prior to use, visually inspect the solution behind a shielded screen for radioprotection purposes. Only use solutions that are clear without visible particles.
16. Keep the vial containing the Gallium Ga 68 Gozetotide Injection upright in a radioprotective shield container at room temperature until use.
17. The final volume of the Gallium Ga 68 Gozetotide Injection is 10 mL after dilution with 0.9% Sodium Chloride Injection.

18. Use within 4 hours if preparation contains less than 2,590 MBq (70 mCi) or within 6 hours if preparation contains 2,590 MBq to 18,500 MBq (70 mCi to 500 mCi).

Figure 1: Drug Preparation with Cyclotron-Produced Ga 68 via GE FASTlab Solid or Liquid Target System



2.6 Preparation with Cyclotron-Produced Ga 68 via ARTMS QIS Solid Target System

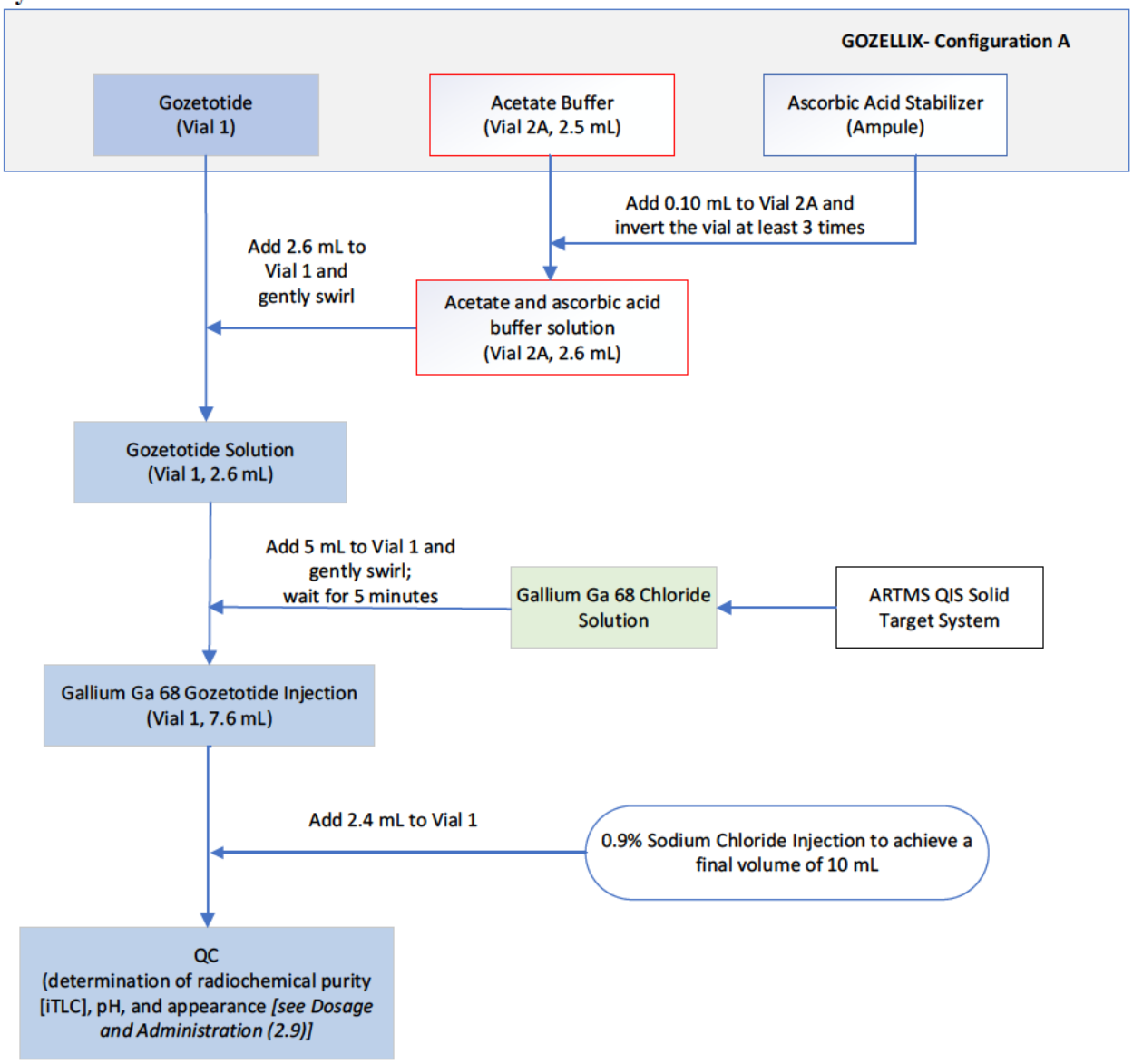
<u>Collection of Gallium Ga 68 Chloride Solution</u>
After purification by the ARTMS QIS, the Gallium Ga 68 Chloride solution is passed through a sterile filter and into the cassette product vial automatically by the ARTMS QIS.

When Ga 68 is cyclotron-produced, test for Ga 66 and Ga 67 (with specification of ≤2% combined total) when a new lot of Zn 68 is introduced for manufacturing.

Radiolabeling Procedure

1. Use GOZELLIX "Configuration A" with cyclotron-produced Ga 68 via ARTMS QIS Solid Target System.
2. A schematic diagram for the preparation is provided in Figure 2.
3. Prepare the acetate buffer (Vial 2A) with ascorbic acid stabilizer as outlined in the procedure above *[see Dosage and Administration (2.4)]*.
4. Pierce Vial 1 (Gozetotide) with a sterile needle connected to a 0.2 micron sterile vented filter to maintain atmospheric pressure within the vial during the reconstitution process.
5. Insert a sterile syringe with a needle into Vial 2A containing the acetate and ascorbic acid buffer solution and draw up 2.6 mL of the solution.
6. Aseptically transfer the acetate and ascorbic acid buffer solution in the syringe into Vial 1 (Gozetotide).
7. Gently swirl Vial 1 to ensure the product is thoroughly dissolved in the buffer.
8. Aseptically transfer the 5 mL of Gallium Ga 68 Chloride solution made using the ARTMS QIS Solid Target System into Vial 1 (Gozetotide).
9. Remove the sterile vent filter.
10. Gently swirl Vial 1 to ensure the product is thoroughly mixed.
11. Wait for 5 minutes for radiolabeling to take place at room temperature (25°C (77°F)); excursions permitted to 15°C to 30°C (59°F to 86°F)).
12. Assay the whole vial containing the Gallium Ga 68 Gozetotide Injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration, and record the result.
13. Dilute the Gallium Ga 68 Gozetotide Injection with 2.4 mL of 0.9% Sodium Chloride Injection to a final volume of 10 mL.
14. Perform the quality control of Gallium Ga 68 Gozetotide Injection according to the recommended methods *[see Dosage and Administration (2.9)]*.
15. Prior to use, visually inspect the solution behind a shielded screen for radioprotection purposes. Only use solutions that are clear without visible particles.
16. Keep the vial containing the Gallium Ga 68 Gozetotide Injection upright in a radioprotective shield container at room temperature until use.
17. The final volume of the Gallium Ga 68 Gozetotide Injection is 10 mL after dilution with 0.9% Sodium Chloride Injection.
18. Use within 4 hours if preparation contains less than 2,590 MBq (70 mCi) or within 6 hours if preparation contains 2,590 MBq to 18,500 MBq (70 mCi to 500 mCi).

Figure 2: Drug Preparation with Cyclotron-Produced Ga 68 via ARTMS QIS Solid Target System



2.7 Preparation with EZAG GalliaPharm Generator

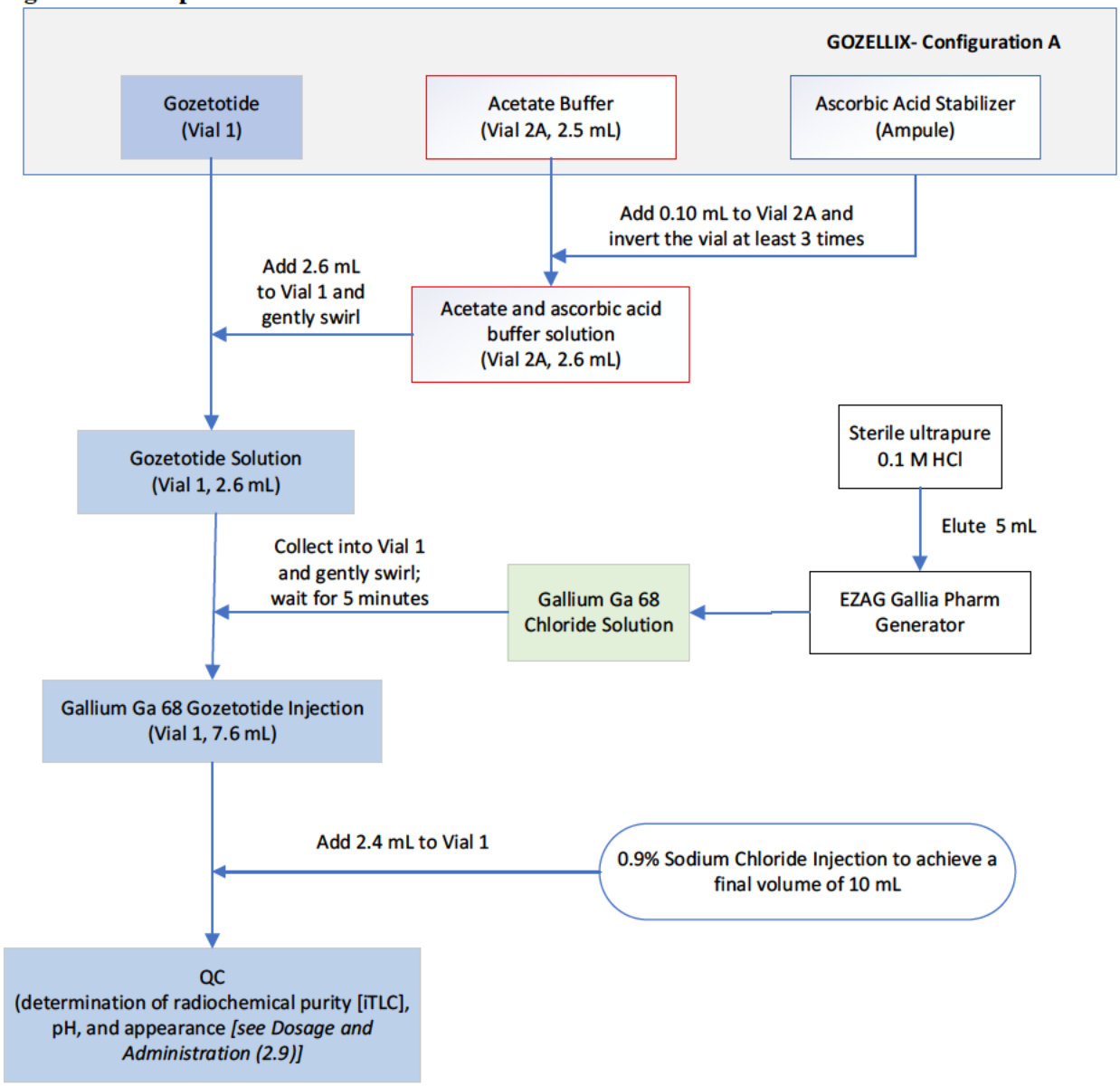
Follow the generator manufacturers' instructions for generator preparation, controls, and continuous routine elution.

Radiolabeling Procedure

1. Use GOZELLIX "Configuration A" with an EZAG GalliaPharm generator.
2. A schematic diagram for the preparation is provided in Figure 3.
3. Prepare the acetate buffer vial (Vial 2A) with ascorbic acid stabilizer as outlined in the procedure above *[see Dosage and Administration (2.4)]*.
4. Pierce Vial 1 (Gozetotide) with a sterile needle connected to a 0.2 micron sterile vented filter to maintain atmospheric pressure within the vial during the reconstitution process.

5. Insert a sterile syringe with a needle into Vial 2A containing the acetate and ascorbic acid buffer solution and draw up 2.6 mL of the solution.
6. Aseptically transfer the acetate and ascorbic acid buffer solution in the syringe into Vial 1 (Gozetotide).
7. Gently swirl Vial 1 to ensure the product is thoroughly dissolved in the buffer.
8. Prepare a syringe containing 5 mL of sterile ultrapure 0.1 M HCl provided with the GalliaPharm generator for elution.
9. Connect the male luer of the outlet line of the GalliaPharm generator to a sterile needle.
10. Connect Vial 1 containing the dissolved gozetotide solution directly to the outlet line of the GalliaPharm generator by pushing the needle through the rubber septum and place the vial in a radiation shielded container.
11. Ensure the vent needle and needle to the generator outlet are pulled up as far as possible to not contact the solution in the vial.
12. Elute the generator directly with the 5 mL 0.1 M HCl from step 8 into Vial 1 according to the instructions for use of the GalliaPharm generator that are supplied by EZAG.
13. At the end of the elution, disconnect the generator from Vial 1 by removing the needle from the rubber septum and remove the sterile vent filter.
14. Gently swirl the vial to ensure the product is thoroughly mixed.
15. Wait for 5 minutes for radiolabeling to take place at room temperature (25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)).
16. Assay the whole vial containing the Gallium Ga 68 Gozetotide Injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration, and record the result.
17. Dilute the Gallium Ga 68 Gozetotide Injection with 2.4 mL of 0.9% Sodium Chloride Injection to a final volume of 10 mL.
18. Perform the quality control of Gallium Ga 68 Gozetotide Injection according to the recommended methods *[see Dosage and Administration (2.9)]*.
19. Prior to use, visually inspect the solution behind a shielded screen for radioprotection purposes. Only use solutions that are clear without visible particles.
20. Keep the vial containing the Gallium Ga 68 Gozetotide Injection upright in a radioprotective shield container at room temperature until use.
21. The final volume of the Gallium Ga 68 Gozetotide Injection is 10 mL after dilution with 0.9% Sodium Chloride Injection.
22. Use within 4 hours if preparation contains less than 2,590 MBq (70 mCi) or within 6 hours if preparation contains 2,590 MBq to 18,500 MBq (70 mCi to 500 mCi).

Figure 3: Preparation with EZAG GalliaPharm Generator



2.8 Preparation with IRE ELiT Galli Eo Generator

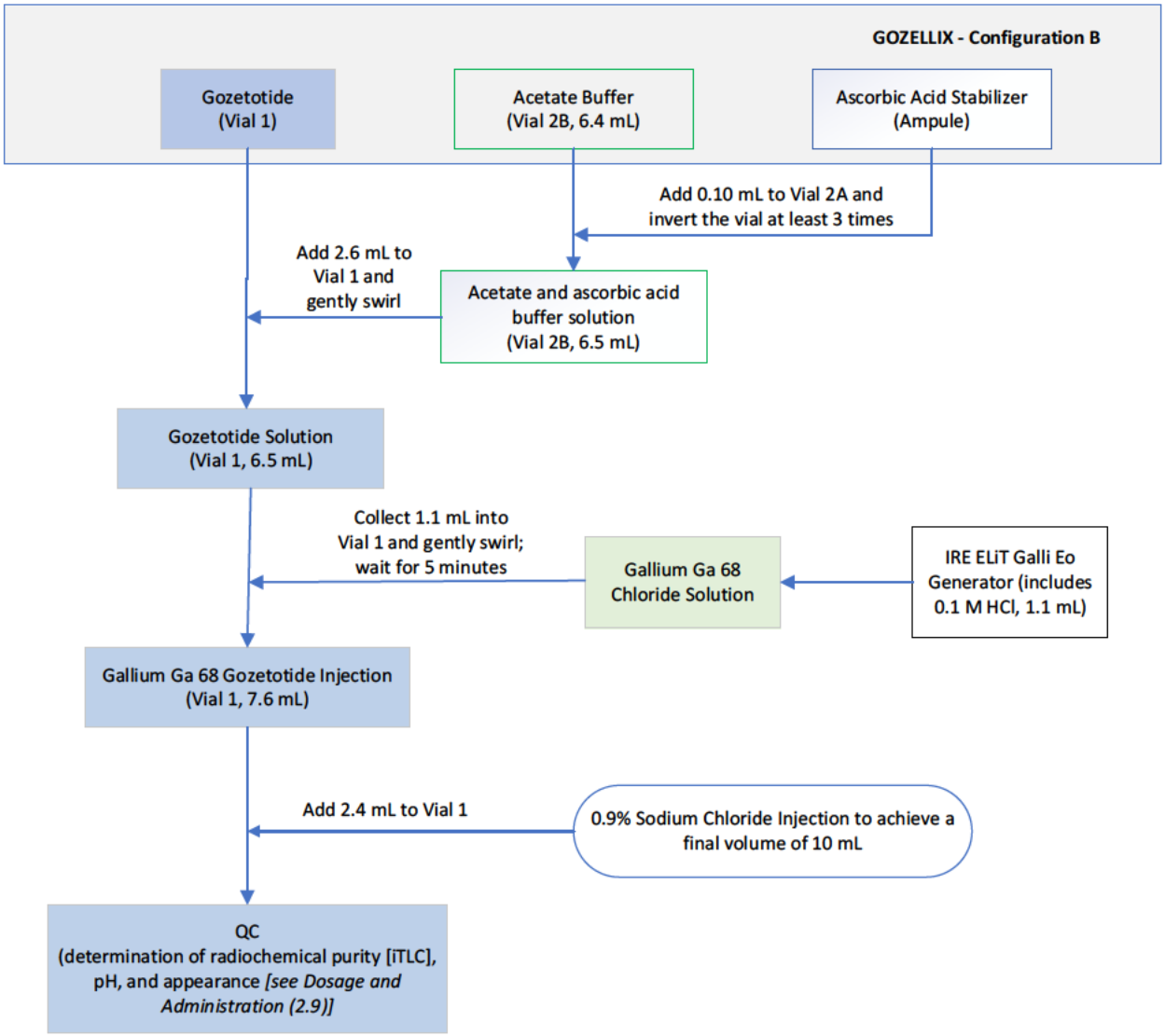
Follow the generator manufacturers' instructions for generator preparation, controls, and continuous routine elution.

<u>Radiolabeling Procedure</u>

1. Use GOZELLIX "Configuration B" with an IRE EliT Galli Eo generator.
2. A schematic diagram for the preparation is provided in Figure 4.
3. Prepare the acetate buffer vial (Vial 2B) with ascorbic acid stabilizer as outlined in the procedure above *[see Dosage and Administration (2.4)]*.
4. Pierce Vial 1 (Gozetotide) with a sterile needle connected to a 0.2 micron sterile vented filter to maintain atmospheric pressure within the vial during the reconstitution process.

5. Insert a sterile syringe with a needle into Vial 2B containing the acetate and ascorbic acid buffer solution and draw up 6.5 mL of the solution.
6. Aseptically transfer the acetate and ascorbic acid buffer solution in the syringe into Vial 1 (Gozetotide).
7. Gently swirl Vial 1 to ensure the product is thoroughly dissolved in the buffer.
8. Remove the 0.2 micron sterile vented filter from Vial 1.
9. Connect the male luer of the outlet line of the Galli Eo generator to a sterile needle.
10. Connect Vial 1 containing the dissolved gozetotide solution directly to the outlet line of the Galli Eo generator by pushing the needle through the vial's septum.
11. Ensure the needle to the generator outlet is pulled up as far as possible to not contact the solution in the vial.
12. Elute 1.1 mL from the generator directly into Vial 1 (Gozetotide) according to the instructions for use of the Galli Eo generator that are supplied by IRE that describe elution into a non-evacuated vial.
13. At the end of the elution, disconnect the generator from Vial 1 by removing the needle from the rubber septum.
14. Gently swirl Vial 1 to ensure the product is thoroughly mixed.
15. Wait for 5 minutes for radiolabeling to take place at room temperature (25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)).
16. Assay the whole vial containing the Gallium 68 Gozetotide Injection for total radioactivity using a dose calibrator, calculate the radioactivity concentration, and record the result.
17. Dilute the Gallium Ga 68 Gozetotide Injection with 2.4 mL of 0.9% Sodium Chloride Injection to a final volume of 10 mL.
18. Perform the quality control of Gallium Ga 68 Gozetotide Injection according to the recommended methods *[see Dosage and Administration (2.9)]*.
19. Prior to use, visually inspect the solution behind a shielded screen for radioprotection purposes. Only use solutions that are clear without visible particles.
20. Keep the vial containing the Gallium Ga 68 Gozetotide Injection upright in a radioprotective shield container at room temperature until use.
21. The final volume of the Gallium Ga 68 Gozetotide Injection is 10 mL after dilution with 0.9% Sodium Chloride Injection.
22. Use within 4 hours if preparation contains less than 2,590 MBq (70 mCi) or within 6 hours if preparation contains 2,590 MBq to 18,500 MBq (70 mCi to 500 mCi).

Figure 4: Preparation with IRE ELiT Galli Eo Generator



2.9 Specifications and Quality Control

Perform the quality controls in Table 2 behind a lead glass shield for radioprotection purposes.

Table 2: Specifications for Gallium Ga 68 Gozetotide Injection

Test	Analytical method	Acceptance criteria
Appearance	Visual examination	Colorless to slightly yellow solution Free from visible particles
pH	pH-meter or pH-strips	4.0 to 5.0
Radiochemical purity • Content of gallium Ga 68 gozetotide • Content of free and colloidal Ga 68	Instant thin-layer chromatography, silica gel (iTLC SG); See methods below	 ≥95% ≤5%

Procedure for instant Thin Layer Chromatography (iTLC)

1. Pour ammonium acetate 1 M/methanol (1/1 v/v) solution to a depth of 3 mm to 4 mm in the developing chamber, cover the chamber and allow it to equilibrate.
2. Prepare an iTLC strip that is 12 cm in length approximately 2.5 cm in width.
3. Using a pencil and ruler, carefully draw a solid line at least 1 cm from the bottom of the iTLC strip.
4. Using a pencil and ruler, carefully draw a solid line 10 cm above the pencil line drawn in Step 3.
5. Using a pencil and ruler, draw a dotted line 2 cm above the solid line at the bottom of the iTLC strip.
6. Using a pencil and ruler, draw a second dotted line 6 cm above the solid line at the bottom of the iTLC strip. Mark the section below this line with an "X". See Figure 5 for an example of how to mark the iTLC strip.
7. Apply a drop of gallium Ga 68 gozetotide solution into the center of the solid line at 1 cm from the bottom of the TLC plate.
8. Place the iTLC strip into the development chamber, with the bottom of the iTLC strip containing drop of gallium Ga 68 gozetotide into the solution at the bottom of the developing chamber. Ensure that the bottom of the iTLC strip sits in the liquid in the chamber, but that the liquid does not touch the drop of gallium Ga 68 gozetotide.
9. Allow the iTLC strip to develop in the covered chamber over a distance of 10 cm from the point of application (until the solvent reaches the solid line near the top of the iTLC strip).
10. Remove the iTLC strip. Allow the plate to dry before proceeding with analysis using one of the methods described below.

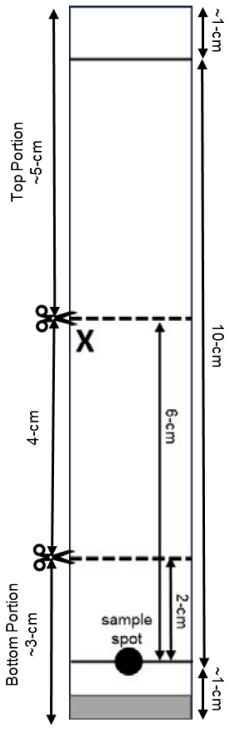
Perform one of the following:

Radiochemical Purity Analysis Using Cutting Technique

1. Cut the iTLC strip into 3 parts by cutting horizontally at the dotted line 2 cm above the solid line at the bottom of the iTLC strip and the dotted line 6 cm above the solid line at the bottom of the iTLC strip. See Figure 5 for where to cut the iTLC strip.
2. This cutting will result in the following 3 portions:
    a. A 3 cm portion containing the Origin and free/colloidal Ga 68 species (Bottom Portion)
    b. A 4 cm portion marked with an "X" containing no sample (this portion is NOT measured)
    c. A 5 cm portion containing the solvent front and gallium Ga 68 gozetotide (Top Portion)
3. Using a dose calibrator or gamma spectrometer, measure and record the radioactivity in the 3 cm portion of the cut TLC plate that contains the Origin and free/colloidal Ga 68 species (Bottom Portion).
4. Using a dose calibrator or gamma spectrometer, measure and record the radioactivity in the 5 cm portion containing the solvent front and gallium Ga 68 gozetotide (Top Portion).
5. Calculate the quantity (in percent) of gallium Ga 68 gozetotide in the solution using the formula:

$$Radiochemical\ Purity\ (\%) = \frac{Counts\ Top\ Portion}{Counts\ from\ Top\ Portion + Counts\ from\ Bottom\ Portion} \times 100$$

Figure 5: iTLC Strip Preparation and Cutting Points for the Cutting Technique



<u>Radiochemical Purity Analysis Using Scanning Technique</u>

1. Scan the iTLC strip with a radiometric iTLC scanner.
2. Calculate the quantity (in percent) of gallium Ga 68 gozetotide in the solution by integration of the peaks on the chromatogram.
3. The retention factor (Rf) specifications are:
   - Free and colloidal Ga 68 species, Rf = 0 to 0.1,
   - Gallium Ga 68 gozetotide, Rf = 0.6 to 1.

2.10 Image Acquisition

Position the patient supine with arms above the head. Begin PET scanning 50 minutes to 100 minutes after the intravenous administration of Gallium Ga 68 Gozetotide Injection. Patients should void immediately prior to image acquisition and image acquisition should begin at the proximal thighs and proceed cranially to the skull base or skull vertex. Adapt imaging technique according to the equipment used and patient characteristics in order to obtain the best image quality possible.

2.11 Image Interpretation

Gallium Ga 68 gozetotide binds to PSMA. Based on the intensity of the signals, PET images obtained using gallium Ga 68 gozetotide indicate the presence of PSMA in tissues. Lesions should be considered suspicious if uptake is greater than physiologic uptake in that tissue or greater than adjacent background if no physiologic uptake is expected. Tumors that do not express PSMA will not be visualized. Increased uptake in tumors is not specific for prostate cancer *[see Warnings and Precautions (5.1)]*.

2.12 Radiation Dosimetry

Estimated radiation absorbed doses per injected activity for organs and tissues of adult male patients following an intravenous bolus of Gallium Ga 68 Gozetotide Injection are shown in Table 3.

The effective radiation dose resulting from the administration of the maximum recommended activity of 259 MBq (7 mCi) is about 4.4 mSv. The radiation doses for this administered activity to the critical organs, which are the kidneys, urinary bladder, and spleen, are 96.2 mGy, 25.4 mGy, and 16.8 mGy, respectively.

These radiation doses are for Gallium Ga 68 Gozetotide Injection alone. If CT or a transmission source are used for attenuation correction, the radiation dose will increase by an amount that varies by technique.

Table 3: Estimated Radiation Absorbed Dose per Injected Activity in Selected Organs and Tissues of Adults after Intravenous Administration of Gallium Ga 68 Gozetotide Injection

	Absorbed dose (mGy/MBq)	
Organ	**Mean**	**SD**
Adrenals	0.0156	0.0014
Brain	0.0104	0.0011
Breasts	0.0103	0.0011
Gallbladder	0.0157	0.0012
Lower Colon	0.0134	0.0009
Small Intestine	0.014	0.002
Stomach	0.0129	0.0008
Heart	0.012	0.0009
Kidneys	0.3714	0.0922
Liver	0.0409	0.0076
Lungs	0.0111	0.0007
Muscle	0.0103	0.0003
Pancreas	0.0147	0.0009
Red Marrow	0.0114	0.0016
Skin	0.0091	0.0003
Spleen	0.065	0.018
Testes	0.0111	0.0006
Thymus	0.0105	0.0006
Thyroid	0.0104	0.0006
Urinary Bladder	0.0982	0.0286
Total Body	0.0143	0.0013
Effective Dose (mSv/MBq)	**0.0169**	**0.0015**

3 DOSAGE FORMS AND STRENGTHS

Kit for the preparation of Gallium Ga 68 Gozetotide Injection contains:

- Vial 1 (Gozetotide): 25 mcg of gozetotide as a white to off-white lyophilized powder in a multiple-dose vial
- Vial 2A (2.5 mL) or Vial 2B (6.4 mL) (Acetate Buffer): 150 mg anhydrous sodium acetate as a sterile clear colorless solution
    - Vial 2A in Configuration A for use with cyclotron-produced Ga 68 via GE FASTlab or ARTMS QIS, or EZAG Gallia Pharm generator
    - Vial 2B in Configuration B for use with IRE EliT Galli Eo generator

- Ampule (Ascorbic Acid Stabilizer): 500 mg/2 mL (250 mg/mL) of ascorbic acid (USP injection grade) as a sterile clear colorless solution

After radiolabeling with Ga 68, Vial 1 contains up to 18,500 MBq (500 mCi) of Gallium Ga 68 Gozetotide Injection in 10 mL at calibration date and time as a clear, colorless to slightly yellow solution in a multiple-dose vial.

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS

5.1 Risk for Misinterpretation
Image interpretation errors can occur with GOZELLIX PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. Gallium Ga 68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. The performance of GOZELLIX for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of GOZELLIX for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score *[*see *Clinical Studies (14.1, 14.2)]*.

Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

5.2 Radiation Risks
Gallium Ga 68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and health care providers. Advise patients to hydrate before and after administration and to void frequently after administration *[see Dosage and Administration (2.1, 2.3)]*.

5.3 Hypersensitivity Reactions to Sulfites
Ascorbic Acid Stabilizer contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

6 ADVERSE REACTIONS

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of GOZELLIX has been established based on two prospective studies of another formulation of gallium Ga 68 gozetotide in patients with prostate cancer *[see Clinical Studies (14.1, 14.2)]*. Below is a display of the adverse reactions in these studies.

The safety of gallium Ga 68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMA-BCR studies, each receiving one dose of gallium Ga 68 gozetotide. The average injected activity was

188.7 ± 40.7 MBq (5.1 ± 1.1 mCi) *[see Clinical Studies (14.1, 14.2)]*. The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

7 DRUG INTERACTIONS

Androgen deprivation therapy and other therapies targeting the androgen pathway
Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga 68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga 68 gozetotide PET has not been established.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
GOZELLIX is not indicated for use in females. There are no available data with gallium Ga 68 gozetotide injection use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. All radiopharmaceuticals, including GOZELLIX, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. Animal reproduction studies have not been conducted with gallium Ga 68 gozetotide.

8.2 Lactation
Risk Summary
GOZELLIX is not indicated for use in females. There are no data on the presence of gallium Ga 68 gozetotide in human milk, the effect on the breastfed infant, or the effect on milk production.

8.4 Pediatric Use
The safety and effectiveness of gallium Ga 68 gozetotide in pediatric patients have not been established.

8.5 Geriatric Use
The efficacy of gallium Ga 68 gozetotide PET in geriatric patients with prostate cancer is based on data from two prospective studies *[see Clinical Studies (14.1, 14.2)]*.

Of the total number of subjects in the PSMA-PreRP and PSMA-BCR studies, 691 of 960 (72%) patients were 65 years of age and older while 195 (20%) were 75 years of age and older.

The efficacy and safety profiles of gallium Ga 68 gozetotide appear similar in younger adult and geriatric patients with prostate cancer and other reported clinical experience has not identified differences in responses between the elderly and younger adult patients.

10 OVERDOSAGE

In the event of an overdose of gallium Ga68 gozetotide, reduce the radiation absorbed dose to the patient where possible by increasing the elimination of the drug from the body using hydration and frequent bladder voiding. A diuretic might also be considered. If possible, an estimate of the radiation effective dose given to the patient should be made.

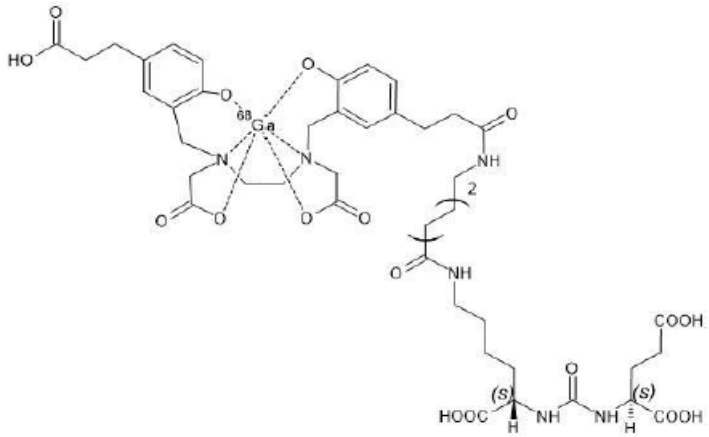
11 DESCRIPTION

11.1 Drug Characteristics

GOZELLIX (kit for the preparation of gallium Ga 68 gozetotide injection), after radiolabeling with Ga 68, is a radioactive diagnostic agent for intravenous use. Gozetotide is also known as PSMA-11.

Gallium Ga 68 gozetotide is a radioconjugate composed of a human prostate specific membrane antigen (PSMA)-targeting ligand peptide conjugated via the acyclic radiometal chelator, N,N'-bis [2-hydroxy-5-(carboxyethyl)benzyl] ethylenediamine-N,N'-diacetic acid (HBED-CC) to the radioisotope Ga 68. The amino acid sequence of the gozetotide peptide is Glu-NH-CO-NH-Lys(Ahx), (Ahx = 6-aminohexanoic acid). Gallium Ga 68 gozetotide has a molecular weight of 1011.9 g/mol and its chemical structure is shown in Figure 6.

Figure 6: Chemical Structure of Gallium Ga 68 Gozetotide



Kit Characteristics

GOZELLIX is supplied as a kit which contains the non-radioactive ingredients needed to produce Gallium Ga 68 Gozetotide Injection. There are two configurations, A or B, available to allow preparation of Gallium Ga 68 Gozetotide Injection using Ga 68 from different generator or cyclotron sources. Each configuration consists of gozetotide (Vial 1), acetate buffer (Vial 2A or Vial 2B), and ascorbic acid stabilizer (Ampule).

- Vial 1 (Gozetotide): Each vial contains 25 mcg gozetotide and 10 mcg D-mannose.
- Vial 2A (Acetate Buffer): Each vial contains 150 mg anhydrous sodium acetate in 2.5 mL of 0.292 M hydrochloric acid.
- Vial 2B (Acetate Buffer): Each vial contains 150 mg anhydrous sodium acetate in 6.4 mL of 0.175 M hydrochloric acid.
- Ampule (Ascorbic Acid Stabilizer): Each ampule contains 500 mg of ascorbic acid (USP injection grade), 3 mg sodium metabisulfite, sodium hydroxide for pH adjustment, and water for injection in a volume of 2 mL.

The prepared Gallium Ga 68 Gozetotide Injection is a sterile, pyrogen free, clear, colorless to slightly yellow, buffered solution containing up to 18,500 MBq (500 mCi) of gallium Ga 68 gozetotide in 10 mL with a pH between 4.0 to 5.0.

11.2 Nuclear Physical Characteristics

Gallium-68 (Ga 68) decays with a half-life of 68 minutes to stable zinc-68. Table 4, Table 5, and Table 6 display the principal radiation emission data, radiation attenuation by lead shielding, and physical decay of Ga 68.

Table 4: Principal Radiation Emission Data (>1%) for Ga 68

Radiation/ Emission	% Disintegration	Mean Energy (MeV)
beta+	88%	0.8360
beta+	1.1%	0.3526
gamma	178%	0.5110
gamma	3.0%	1.0770
X-ray	2.8%	0.0086
X-ray	1.4%	0.0086

Table 5: Radiation Attenuation of 511 keV Photons by Lead (Pb) Shielding

Shield Thickness (Pb) mm	Coefficient of Attenuation
6	0.5
12	0.25
17	0.1
34	0.01
51	0.001

Table 6: Physical Decay Chart for Ga 68

Minutes	Fraction Remaining
0	1
15	0.858
30	0.736
60	0.541
90	0.398
120	0.293
180	0.158
360	0.025

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Gallium Ga 68 gozetotide binds to PSMA. It binds to cells that express PSMA, including malignant prostate cancer cells, which usually overexpress PSMA. Gallium-68 is a β+ emitting radionuclide that allows positron emission tomography.

12.2 Pharmacodynamics

The relationship between gallium Ga 68 gozetotide plasma concentrations and successful imaging was not explored in clinical trials.

12.3 Pharmacokinetics

Distribution

Intravenously injected gallium Ga 68 gozetotide is cleared from the blood and is accumulated preferentially in the liver (15%), kidneys (7%), spleen (2%), and salivary glands (0.5%). Gallium Ga 68 gozetotide uptake is also seen in the adrenals and prostate. There is no uptake in the cerebral cortex or in the heart, and usually lung uptake is low.

Elimination

A total of 14% of the injected dose is excreted in urine in the first 2 hours post-injection.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies were performed to evaluate the carcinogenicity potential of gallium Ga 68 gozetotide.

14 CLINICAL STUDIES

14.1 Imaging Prior to Initial Definitive Therapy

The efficacy of GOZELLIX for PET of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy has been established based on a study of another formulation of gallium Ga 68 gozetotide. Below is a display of the results of the prospective, open label study PSMA-PreRP (NCT03368547 and NCT02919111).

This two-center study enrolled 325 patients with biopsy-proven prostate cancer who were considered candidates for prostatectomy and pelvic lymph node dissection. All enrolled patients met at least one of the following criteria: serum prostate-specific antigen (PSA) of at least 10 ng/mL, tumor stage cT2b or greater, or Gleason score greater than 6. Each patient received a single gallium Ga 68 gozetotide PET/CT or PET/MR from mid-thigh to skull base.

A total of 123 patients (38%) proceeded to standard-of-care prostatectomy and template pelvic lymph node dissection and had sufficient histopathology data for evaluation (evaluable patients). Three members of a pool of six central readers independently interpreted each PET scan for the presence of abnormal gallium Ga 68 gozetotide uptake in pelvic lymph nodes located in the common iliac, external iliac, internal iliac, and obturator subregions bilaterally as well as in any other pelvic location. The readers were blinded to all clinical information except for the history of prostate cancer prior to definitive treatment. Extrapelvic sites and the prostate gland itself were not analyzed in this study. For each patient, gallium Ga 68 gozetotide PET results and reference standard histopathology obtained from dissected pelvic lymph nodes were compared by region (left hemipelvis, right hemipelvis, and other).

For the 123 evaluable patients, the mean age was 65 years (range 45 to 76 years), and 89% were white. The median serum PSA was 11.8 ng/mL. The summed Gleason score was 7 for 44%, 8 for 20%, and 9 for 31% of the patients, with the remainder of the patients having Gleason scores of 6 or 10.

Table 7 compares majority PET reads to pelvic lymph node histopathology results at the patient-level with region matching, such that at least one true positive region defines a true positive patient. As shown, approximately 24% of subjects studied were found to have pelvic nodal metastases based on histopathology (95% confidence interval: 17%, 32%).

Table 7: Patient-Level Performance of Gallium Ga 68 Gozetotide PET for Detection of Pelvic Lymph Node Metastasis* in the PSMA-PreRP Study (n=123)

		Histopathology		Predictive value** (95% CI)
		Positive	Negative	
PET scan	Positive	14	9	PPV 61% (41%, 81%)
	Negative	16	84	NPV 84% (79%, 91%)
Total		30	93	
Diagnostic performance (95% CI)		Sensitivity 47% (29%, 65%)	Specificity 90% (84%, 96%)	

*with region matching where at least one true positive region defines a true positive patient
**PPV: positive predictive value, NPV: negative predictive value

Among the pool of six readers, sensitivity ranged from 36% to 60%, specificity from 83% to 96%, positive predictive value from 38% to 80%, and negative predictive value from 80% to 88%.
In an exploratory subgroup analysis based on summed Gleason score, there was a numerical trend toward more true positives in patients with Gleason score of 8 or higher compared to those with Gleason score of 7 or lower.

An exploratory analysis was performed to estimate the sensitivity and specificity for pelvic nodal metastasis detection in all scanned patients, including the patients who were lacking histopathology reference standard. An imputation method was used based on patient-specific factors. This exploratory analysis resulted in an imputed sensitivity of 47%, with a 95% confidence interval ranging from 38% to 55%, and an imputed specificity of 74%, with a 95% confidence interval ranging from 68% to 80% for all patients imaged with gallium Ga 68 gozetotide PET.

14.2 Imaging Prior to Suspected Recurrence Therapy
The efficacy of GOZELLIX for PET of PSMA-positive lesions in men with prostate cancer with suspected recurrence based on elevated serum PSA level has been established based on a study of another formulation of gallium Ga 68 gozetotide. Below is a display of the results of the prospective, open label study PSMA-BCR (NCT02940262 and NCT02918357).

This two-center study enrolled 635 patients with biochemical evidence of recurrent prostate cancer after definitive therapy, defined by serum PSA of >0.2 ng/mL more than 6 weeks after prostatectomy or by an increase in serum PSA of at least 2 ng/mL above nadir after definitive radiotherapy. All patients received a single gallium Ga 68 gozetotide PET/CT or PET/MR from mid-thigh to skull base. Three members of a pool of nine independent central readers evaluated each scan for the presence and regional location (20 subregions grouped into four regions) of abnormal gallium Ga 68 gozetotide uptake suggestive of recurrent prostate cancer. The readers were blinded to all clinical information other than type of primary therapy and most recent serum PSA level.

A total of 469 patients (74%) had at least one positive region detected by gallium Ga 68 gozetotide PET majority read. The distribution of gallium Ga 68 gozetotide PET positive regions was 34% bone, 25% prostate bed, 25% pelvic lymph node, and 17% extrapelvic soft tissue. Two hundred and ten patients had composite reference standard information collected in a PET positive region (evaluable patients), consisting of at least one of the following: histopathology, imaging (bone scintigraphy, CT, or MRI) acquired at baseline or within 12 months after gallium Ga 68 gozetotide PET, or serial serum PSA.

Composite reference standard information for gallium Ga 68 gozetotide PET negative regions was not systematically collected in this study.

In the 210 evaluable patients, the mean age was 70 years (range 49 to 88 years) and 82% were 65 years of age or older. White patients made up 90% of the group. The median serum PSA was 3.6 ng/mL. Prior treatment included radical prostatectomy in 64% and radiotherapy in 73%.

Of the 210 evaluable patients, 192 patients (91%) were found to be true positive in one or more regions against the composite reference standard (95% confidence interval: 88%, 95%). Among the pool of nine readers used in the study, the proportion of patients who were true positive in one or more regions ranged from 82% to 97%. The prostate bed had the lowest proportion of true positive results at the region-level (76% versus 96% for non-prostate regions).

An exploratory analysis was also performed in which gallium Ga 68 gozetotide PET positive patients who lacked reference standard information were imputed using an estimated likelihood that at least one location-matched PET positive lesion was reference standard positive based on patient-specific factors. In this exploratory analysis, 340 of 475 patients (72%) were imputed as true positive in one or more regions (95% confidence interval: 68%, 76%).

In another exploratory analysis using the same imputation approach for PET positive patients who lacked reference standard information, 340 of 635 patients (54%) were correctly detected as true positive (95% confidence interval: 50%, 57%) among all BCR patients who received a PET scan, whether it was read as positive or negative.

The likelihood of identifying a gallium Ga 68 gozetotide PET positive lesion in this study increased with higher serum PSA level. Table 8 shows the patient-level gallium Ga 68 gozetotide PET results stratified by serum PSA level. The mean time between PSA measurement and PET scan was 40 days with a range of 0 to 367 days. Percent PET positivity was calculated as the proportion of patients with a positive gallium Ga 68 gozetotide PET out of all patients scanned. Percent PET positivity includes patients determined to be either true positive or false positive as well as those in whom such determination was not made due to the absence of composite reference standard data.

Table 8: Patient-Level Gallium Ga 68 Gozetotide PET Results and Percent PET Positivity Stratified by Serum PSA Level in the PSMA-BCR Study (n=628)*

PSA (ng/mL)	**PET positive patients**				**PET negative patients**	**Percent PET positivity*** (95% CI)**
	Total	TP**	FP**	Without reference standard		
		With reference standard				
<0.5	48	11	1	36	87	36% (27%, 44%)
		12				
≥0.5 and <1	44	15	3	26	35	56% (45%, 67%)
		18				
≥1 and <2	71	29	1	41	15	83% (75%, 91%)
		30				
≥2	299	137	13	149	29	91% (88%, 94%)
		150				
Total	462	192	18	252	166	74% (70%, 77%)
		210				

*7 patients were excluded from this table due to protocol deviations

**TP: true positive, FP: false positive
***Percent PET positivity = PET positive patients/total patients scanned

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied
GOZELLIX (kit for the preparation of gallium Ga 68 gozetotide injection) is available in two different configurations.

GOZELLIX Configuration "A" (NDC 84552-500-25), intended for use with Ga 68 produced from a cyclotron and purified via GE FASTlab or ARTMS QIS, or an Eckert & Ziegler GalliaPharm Ge 68/Ga 68 generator, contains:

- Vial 1 (Gozetotide): 25 mcg gozetotide as a sterile white to off-white lyophilized powder in a multiple-dose vial with a blue flip-off cap (NDC 84552-501-25)
- Vial 2A (Acetate Buffer): 150 mg/2.5 mL of anhydrous sodium acetate as a sterile clear colorless solution in a vial with a red flip off cap (NDC 84552-502-25)
- Ampule (Ascorbic Acid Stabilizer): 500 mg/2 mL (250 mg/mL) of ascorbic acid (USP injection grade) as a sterile clear colorless solution in a glass ampule (NDC 84552-504-25)

GOZELLIX Configuration "B" (NDC 84552-500-64), intended for use with Ga 68 produced from an IRE Galli Eo Ge 68/Ga 68 generator, contains:

- Vial 1 (Gozetotide): 25 mcg gozetotide as a sterile white to off-white lyophilized powder in a multiple-dose vial with a blue flip-off cap (NDC 84552-501-25)
- Vial 2B (Acetate Buffer): 150 mg/6.4 mL of anhydrous sodium acetate as a sterile clear colorless solution in a vial with a green flip off cap (NDC 84552-503-64)
- Ampule (Ascorbic Acid Stabilizer): 500 mg/2 mL (250 mg/mL) of ascorbic acid (USP injection grade) as a sterile clear colorless solution in a glass ampule (NDC 84552-504-25)

The radionuclide is not part of the kit. Before radiolabeling with Ga 68, the contents of this kit are not radioactive.

Storage and Handling
Store GOZELLIX refrigerated upright in the original packaging at 2° to 8°C (36° to 46°F). Do not freeze.

After radiolabeling, keep Gallium Ga 68 Gozetotide Injection upright with appropriate shielding to protect from radiation at room temperature (25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)). Use Gallium Ga 68 Gozetotide Injection within the time frames described in Table 9 below.

Table 9: Shelf Life Per Activity of Gallium Ga 68 Gozetotide Injection

Activity	Shelf Life
Less than 2,590 MBq (70 mCi)	4 hours
2,590 MBq to 18,500 MBq (70 mCi to 500 mCi)	6 hours

Dispose of the product in accordance with all federal, state, and local laws and institutional requirements.

This preparation is approved for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

17 PATIENT COUNSELING INFORMATION

Adequate Hydration

Instruct patients to drink a sufficient amount of water to ensure adequate hydration before their PET study and urge them to drink and urinate as often as possible during the first hours following the administration of Gallium Ga 68 Gozetotide Injection, in order to reduce radiation exposure *[see Dosage and Administration (2.3)* and *Warnings and Precautions (5.2)]*.

Manufactured for:
Telix Innovations SA
rue de Hermée 255 à 4040 Herstal, Belgium

For optional information on GOZELLIX, see www.gozellix.com.

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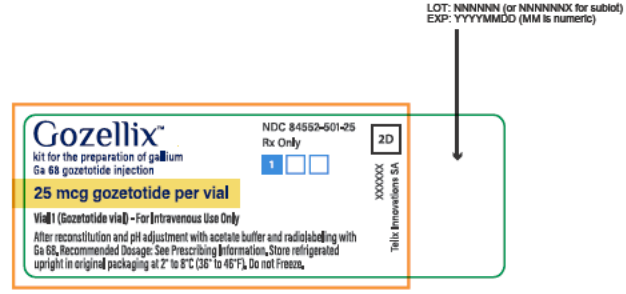
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EXP: YYYYMMDD (MM is numeric)
Gozellix™
kit for the preparation of gallium
Ga 68 gozetotide injection
NDC 84552-501-25
Rx Only
1
2D
25 mcg gozetotide per vial
Vial 1 (Gozetotide vial) - For Intravenous Use Only
After reconstitution and pH adjustment with acetate buffer and radiolabeling with
Ga 68, Recommended Dosage: See Prescribing Information. Store refrigerated
upright in original packaging at 2° to 8°C (36° to 46°F). Do not Freeze.
XXXXXX
Telix Innovations SA

LOT: NNNNNN (or NNNNNNX for sublot)
EXP: YYYYMMDD (MM is numeric)

For pH adjustment of Gozellix™

2.5 mL

NDC 84552-502-25
Rx Only

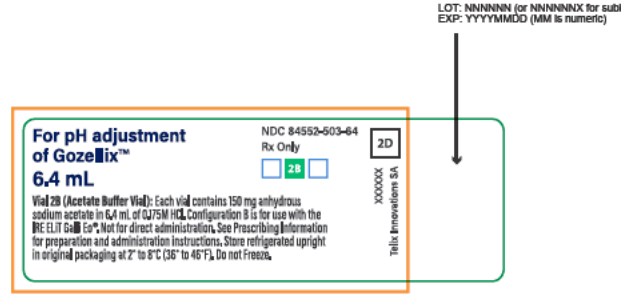
2A

2D

XXXXXX

Telix Innovations SA

Vial 2A (Acetate Buffer Vial): Each vial contains 150 mg anhydrous sodium acetate in 2.5 mL of 0.292M HCl. Configuration A is for use with the EZAG GalliaPharm® or Ga 68 produced by cyclotron using GE liquid or solid target, or ARTMS solid target. Not for direct administration. See Prescribing Information for preparation and administration instructions. Store refrigerated upright in original packaging at 2° to 8°C (36° to 46°F). Do not Freeze.


LOT: NNNNNN (or NNNNNNX for sublot)
EXP: YYYYMMDD (MM is numeric)
For pH adjustment of Gozellix™
6.4 mL
NDC 84552-503-64
Rx Only
2B
2D
Vial 2B (Acetate Buffer Vial): Each vial contains 150 mg anhydrous sodium acetate in 6.4 mL of 0.175M HCl. Configuration B is for use with the RE ELIT Gallium Ea®. Not for direct administration. See Prescribing Information for preparation and administration instructions. Store refrigerated upright in original packaging at 2° to 8°C (36° to 46°F). Do not Freeze.
XXXXXX
Telix Innovations SA

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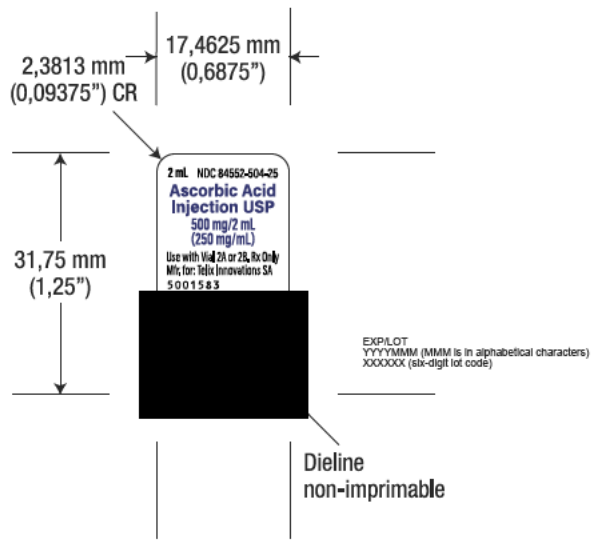
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2,3813 mm
(0,09375”) CR
31,75 mm
(1,25”)
2 mL NDC 84552-504-25
Ascorbic Acid
Injection USP
500 mg/2 mL
(250 mg/mL)
Use with Vial 2A or 2B, Rx Only
Mfr. for: Telix Innovations SA
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EXP/LOT
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Dieline
non-imprimable

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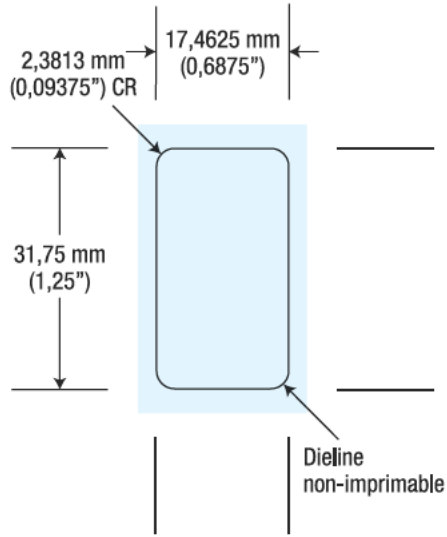
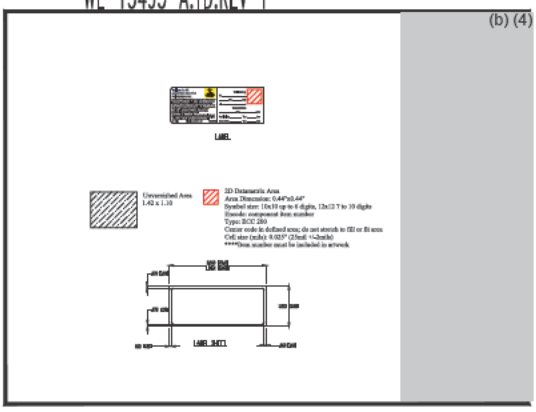


Reference ID: 5550819

WL-13495 A.TD.REV 1

(b) (4)



Gallium Ga 68 gozetotide Injection

Rx Only

APPLY TO SYRINGE

See Prescribing Information before use. Use within 4 hours after radiolabeling if preparation contains < 2,590 MBq (< 70 mCi), or 6 hours after radiolabeling if preparation contains 2,590 MBq to 18,500 MBq (70 mCi to 500 mCi).

Patient Name.....

LOT..... Radiolabeling.....

XXXXXX

Reference ID: 5550819

RD-13144 B.TD.REV 1

(b) (4)

Variable Print Area:
-Black
-Unvarnished
-2.36" x 0.63"

TE Seal Area:
-Unvarnished
-5/8 size half circle

2D Datamatrix Area
Area Dimension: 0.44"x0.44"
Symbol size: 10x10 up to 6 digits, 12x12 7 to 10 digits
Encode: component item number
Type: ECC 200
Center code in defined area; donot stretch to fill or fit area
Cell size (mils): 0.025" (25mil +/-2mils)
****Item number must be included in artwork

RD-13144 B.TD.REV 1

Gozellix
kit for the preparation of gallium Ga 68 gozetotide injection
25 mcg/vial gozetotide
Rx Only
NDC 84592-500-54
For Intravenous Use Only

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

AUGUST A HOFLING
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