Isoprotrace®

Kit for the preparation of Gallium (^{68}Ga) Gozetotide

Simplicity Meets Diagnostic Excellence

An advanced PSMA-11 radiolabelling kit for prostate cancer imaging

isotopia
Nuclear Medicine

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Isoprotrace® Product Overview And Indications

Isoprotrace® is an advanced PSMA-11 radiolabelling kit specifically designed for prostate cancer imaging. This ready-to-use, multi-dose kit allows for the efficient preparation of Gallium (68Ga) Gozetotide solution for I.V. injection.

Product Overview

- **Active Ingredient:** 10µg Gozetotide (PSMA-11)
- **Kit Presentation:** Multi-dose sterile vacuum vial
- **The package contains:** 5 vials
- **Shelf Life:** 2 years

Streamlined Workflow:

- **5-Minute Preparation:** Rapid, efficient process from start to finish
- **One Vial, Two Steps:** Simplicity redefined with our ready-to-use kit
- **Multi-Dose Capability:** Preparation of multiple patient doses from a single kit

Isoprotrace® is indicated for PET imaging of PSMA - positive lesions in adult men with prostate cancer:

- Primary staging of patients with high risk prostate cancer prior to primary curative therapy.
- Suspected prostate cancer recurrence based on elevated serum prostate-specific antigen (PSA) level, after primary curative therapy.

Why Isoprotrace®: Fast, Efficient, Reliable

High-Precision PSMA Biomarker: Contains PSMA-11, an ideal biomarker for precise prostate cancer diagnosis and effective disease management.

Resources and Time Saving: Minimal product loss (over 99% yield, decay corrected) due to faster preparation time and minimal handling.

Single Sterile Vacuum Vial: Technician friendly, ready-to-use, single vacuum vial that simplifies a reproducible labelling process.

Easy and Rapid Multi-Dose Preparation: Economically attractive, multi-dose preparation performed in just 5 minutes.

Simplified Fast QC: RCP with ITLC (no HPLC needed), fewer QC tests required.

Quality Assured: Produced in a facility that is inspected by the FDA and complies with EU GMP.

PSMA: A Key Biomarker in Prostate Cancer

Prostate-Specific Membrane Antigen (PSMA) is an important biomarker in prostate cancer.

This protein is found on the surface of prostate cells and becomes significantly more abundant in cancerous tissues. Over 80% of prostate cancers exhibit high levels of PSMA making it a valuable tool for detecting and monitoring the disease. Its high expression in prostate cancer, combined with its limited presence in most normal tissues, establishes PSMA as a reliable indicator, enhancing the accuracy of prostate cancer diagnosis and care[1].

PSMA-11: The Gold Standard in Prostate Cancer Imaging

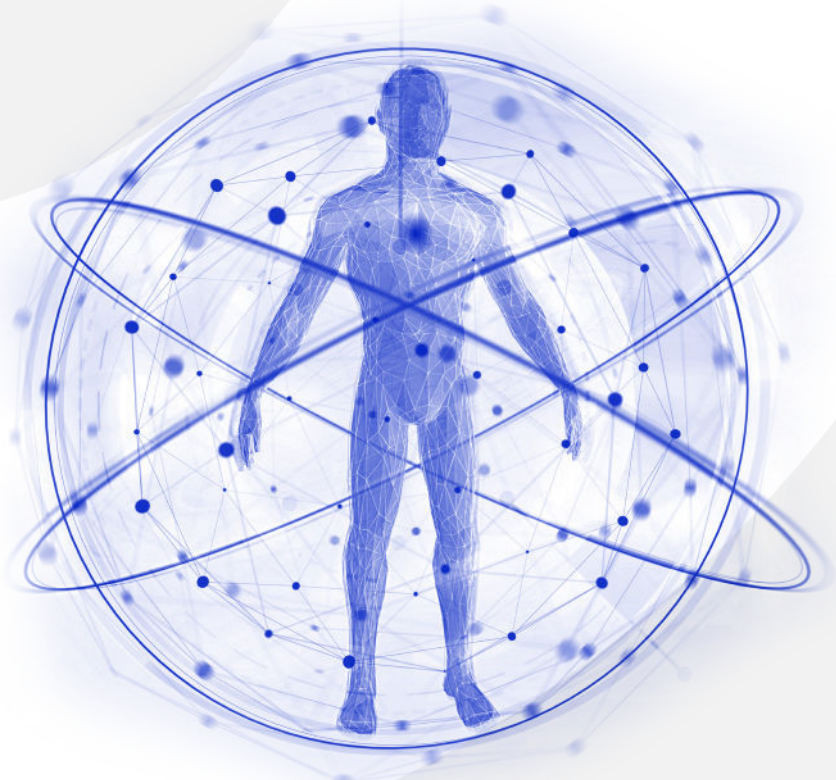
PSMA-11 is the most widely used and researched PSMA probe for prostate cancer imaging, and it was the first to receive FDA approval on December 1, 2020.

Imaging Findings

PSMA-11 demonstrates a significantly reduced false positive rate compared to alternatives.
In a comparative study, 18F-PSMA-1007 PET revealed approximately five times more benign lesions attributed to non-cancerous origins than 68Ga-PSMA-11 PET (245 vs. 52 lesions, respectively)[2].

Clinical Impact

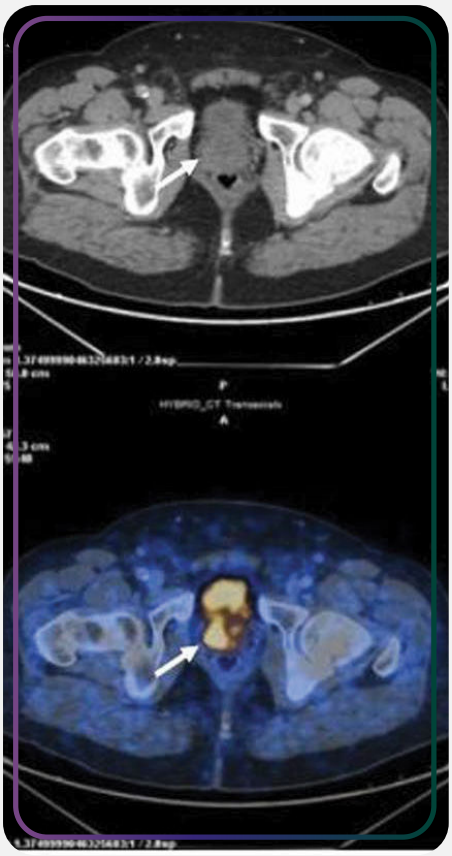
This higher specificity of PSMA-11 leads to more accurate staging and treatment planning, ultimately improving patient outcomes[3].



Advanced Imaging: Detecting Prostate Cancer with Isoprotrace®

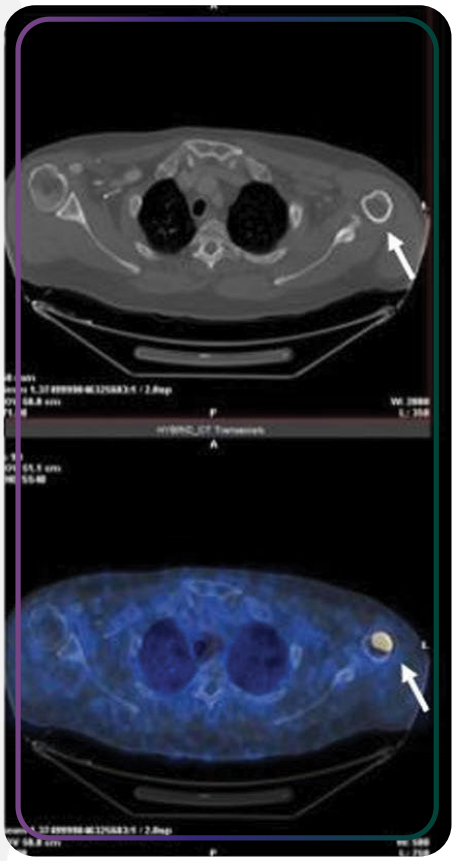
The following images illustrate various sites of pathological **Isoprotrace®** uptake, showcasing the diagnostic utility of this advanced imaging radiotracer[4].

Prostate Tumor



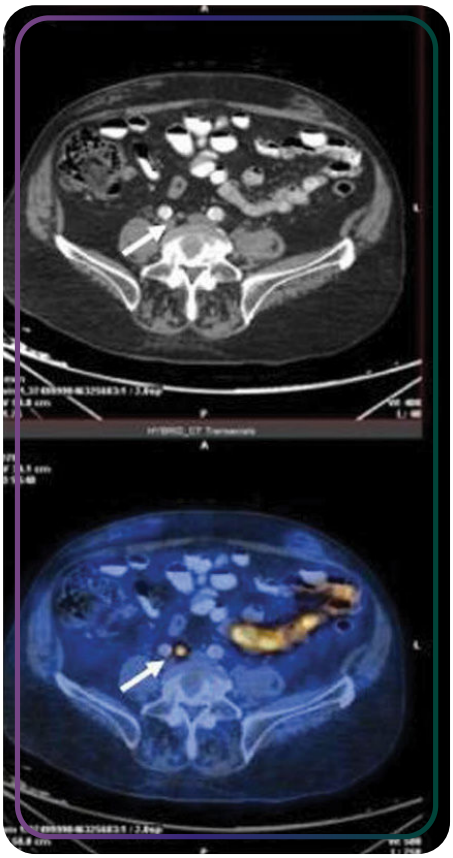
This image depicts a primary prostate tumor and demonstrates the effectiveness of **Isoprotrace®** in identifying cancerous tissues, thereby facilitating accurate diagnosis and informing treatment decisions.

Bone Metastasis



This image illustrates bone marrow metastasis in the left proximal humerus, which was undetectable by conventional CT imaging, emphasizing the superior sensitivity of PET imaging with **Isoprotrace®**.

Lymph Node Metastasis



This image presents a 7mm pelvic lymph node metastasis, further underscoring the kit's ability to detect even small metastatic lesions, facilitating timely and accurate diagnosis and treatment planning.

Enhanced Efficiency and Simplicity: Advancements with the Isoprotrace® vs. Module-based Synthesis of Gallium-68 PSMA

A study highlights the advantages of the **Isoprotrace®** Cold Kit in the synthesis of Ga-68 PSMA compared to traditional module-based methods[5].

Key Significant Findings:

Production Time: The preparation time for **Isoprotrace®** (incubation only) is 5.01 minutes, significantly faster than the 15.7 minutes required for module-based synthesis.

Total Radiochemical Yield: **Isoprotrace®** delivers an exceptional radiochemical yield, demonstrating superior efficiency over conventional methods. This is achieved through the direct elution of the $^{68}Ge/^{68}Ga$ generator into the kit, which minimizes product loss and further enhances the yield of Gallium-68 PSMA, resulting in up to 15% more end-product activity.

Overall Efficiency: Utilizing the lyophilized kit significantly increases production efficiency, allowing for the delivery of more Gallium-68 PSMA to patients in need.

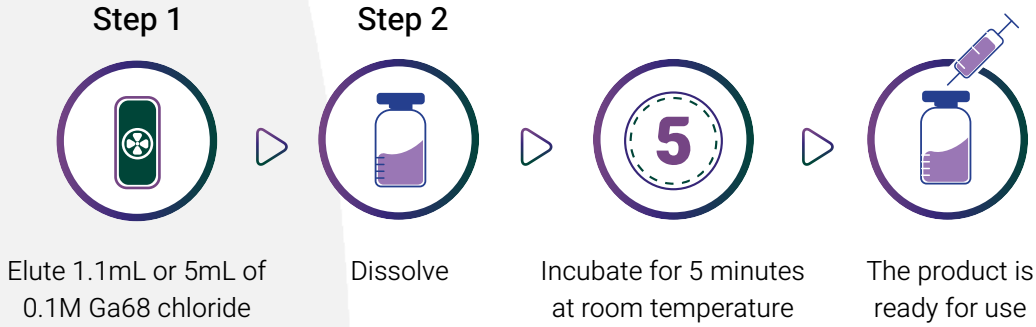
These findings demonstrate that **Isoprotrace®** effectively streamlines production processes while ensuring reliable, high-quality results.

How to Prepare Isoprotrace®?

Isoprotrace® offers unparalleled convenience with on-site preparation.

The process is remarkably efficient:

- **Preparation time:** Only 5 minutes (excluding elution)
- **Simplicity:** 1 vial, 2 simple preparation steps



*Detailed Instructions: Refer to SmPC for comprehensive preparation instructions.

Technical Information

- **Radiolabelling:** With Gallium (68Ga) chloride
- **Generator Compatibility:** Fully compatible with both 68Ge / 68Ga generators approved in Europe, GalliaPharm® and Galli Ad.
- **Quality Control:** RCP with ITLC (no HPLC needed), fewer QC tests required (no endotoxin and sterility tests needed)
- **Storage and Handling:**
  - **Before reconstitution:** Store in a refrigerator (2°C – 8°C)
  - **After radiolabelling:** Stable up to 4 hours at room temperature

Regulatory Information

Approval Status: **Isoprotrace®** has received marketing authorization in the Netherlands and Germany with pending approvals in more EU countries.

About Isotopia Molecular Imaging

Isotopia Nuclear Medicine, established in 2006, is a global leader in innovative radiopharmaceuticals for diagnostics and therapy. We specialize in producing radioisotopes and Cold Kits, with a focus on innovative products and continuous R&D in molecular imaging. Our global distribution network ensures widespread availability of our high-quality products. As part of our commitment to meet worldwide demand, we are actively expanding our production facilities across the globe. As the manufacturer of **Isoprotrace®**, Isotopia is dedicated to advancing nuclear medicine and improving patient care in oncology through cutting-edge diagnostic tools.

For detailed information, please refer to the product's SmPC.
For more information please contact:
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References:

1. Hofman, Michael S et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomized, multicentre study. The Lancet, Volume 395, Issue 10231, 1208 - 1216
2. Rauscher, I., et al. (2020). Comparison of 68Ga-PSMA-11 and 18F-PSMA-1007 for Prostate Cancer Imaging. Journal of Nuclear Medicine, 2020 Jan;61(1):51-57.
3. Purysko AS, Abreu AL, Lin DW, Punnen S. Not All Prostate-Specific Membrane Antigen Imaging Agents Are Created Equal: Diagnostic Accuracy of Ga-68 PSMA-11 PET/CT for Ini Appl Radiol. 2024;53(2):22-35.
4. Marina Muchnik Kurash, Ronit Gill, Maria Khairulin, Hanan Harbosh & Zohar Keidar. 68Ga-labeled PSMA-11 (68GaisoPROtrace-11) synthesized with ready to use kit: normal biodistribution and uptake characteristics of tumor lesions. Scientific Reports. (2020) 10:3019.
5. Golan H, Esa M, Moshkoviz K, Feldhaim A, Hoch B, Shalom E. Enhancing capacity and synthesis of [68Ga]68-Ga-PSMA-HBED-CC with the lyophilized ready-to-use kit for nuclear pharmacy applications. Nucl Med Commun. 2020 Sep;41(9):986-990.

Name of the medicinal product: Isoprotrace 10 micrograms, kit for radiopharmaceutical preparation. **Qualitative and quantitative composition**: Each vial contains gozetotide trifluoroacetate equivalent to 10 micrograms of gozetotide. **List of excipients**: Sodium acetate anhydrous, sodium chloride, hydrolysed gelatine. **Therapeutic indications:** After radiolabelling with gallium (68Ga) chloride solution, gallium (68Ga) gozetotide is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer in the following clinical settings: Primary staging of patients with high risk prostate cancer prior to primary curative therapy, and suspected prostate cancer recurrence based on elevated serum prostate-specific antigen (PSA) level, after primary curative therapy. **Contraindications:** Hypersensitivity to the active substance, to any of the excipients listed or to any of the components of the labelled radiopharmaceutical. **Interaction with other medicinal products and other forms of interaction:** Based on the extremely low mass dose of not more than 10 mcg single dose, gallium (68Ga) gozetotide is not expected to have any clinically significant interaction with other medicinal products. No interaction studies have been performed. Androgen deprivation therapy (ADT) and other therapies targeting athe androgen receptor pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium (68Ga) gozetotide in prostate cancer. The effect of these therapies on performance of gallium (68Ga) gozetotide PET has not been established. **Undesirable effects:** Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose, resulting from the administration of an average activity of 2 MBq/kg to an 80 kg man is 3.5 mSv, these adverse reactions are expected to occur with a low probability. Mild to moderate adverse reactions occurred in patients receiving gallium (68Ga) gozetotide. The most commonly reported reactions were fatigue, headache, injection site reactions, nausea and rash. Uncommon adverse events (≥1/1000 to <1/100) are headache, dizziness, paraesthesia, insomnia, nausea, diarrhoea, dysphagia, rash, fatigue, and injection site reactions. **Marketing Authorisation Holder:** Billev Pharma ApS, Slotsmarken10, 2970 Hørsholm, Denmark. **Marketing Authorisation numbers:** Netherlands: RVG 130527, Germany: 7011054.
General classification for supply: prescription. **Date of revision of the text:** 03.2024

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