This is a current list of all FDA-approved radiopharmaceuticals. Nuclear medicine practitioners that receive radiopharmaceuticals that originate from sources other than the manufacturers listed in these tables may be using unapproved copies.

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Manufacturer</th>
<th>Trade Names</th>
<th>Approved Indications in Adults (Pediatric use as noted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon-11 choline</td>
<td>Mayo Clinic</td>
<td>–</td>
<td>Indicated for PET imaging of patients with suspected prostate cancer recurrence based upon elevated blood prostate specific antigen (PSA) levels following initial therapy and non-informative bone scintigraphy, computerized tomography (CT) or magnetic resonance imaging (MRI) to help identify potential sites of prostate cancer recurrence for subsequent histologic confirmation</td>
</tr>
<tr>
<td>Carbon-14 urea</td>
<td>Kimberly-Clark</td>
<td>PYtest</td>
<td>Detection of gastric urease as an aid in the diagnosis of H.pylori infection in the stomach</td>
</tr>
<tr>
<td>Fluorine-18 florbetaben</td>
<td>Piramal Imaging</td>
<td>Neuraceq™</td>
<td>Indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease (AD) or other causes of cognitive decline</td>
</tr>
<tr>
<td>Fluorine-18 florbetapir</td>
<td>Eli Lilly</td>
<td>Amyvid™</td>
<td></td>
</tr>
<tr>
<td>Fluorine-18 sodium fluoride¹</td>
<td>Various</td>
<td>–</td>
<td>PET bone imaging agent to delineate areas of altered osteogenesis</td>
</tr>
<tr>
<td>Radiopharmaceutical</td>
<td>Manufacturer</td>
<td>Trade Names</td>
<td>Approved Indications in Adults (Pediatric use as noted)</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------</td>
<td>-------------</td>
<td>--------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 6 Fluorine-18 fludeoxyglucose¹ | Various | – | As a PET imaging agent to:  
• Assess abnormal glucose metabolism in oncology  
• Assess myocardial hibernation  
• Identify regions of abnormal glucose metabolism associated with foci of epileptic seizures |
| 7 Fluorine-18 flutemetamol | GE Healthcare | Vizamyl | Indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease (AD) or other causes of cognitive decline |
| 8 Gallium-67 citrate | Coviden | – | Useful to demonstrate the presence/extent of:  
• Hodgkin’s disease  
• Lymphoma  
• Bronchogenic carcinoma  
Aid in detecting some acute inflammatory lesions |
| 9 Indium-111 capromab pendetide | Jazz Pharmaceuticals | ProstaScint® | • A diagnostic imaging agent in newly-diagnosed patients with biopsy-proven prostate cancer, thought to be clinically-localized after standard diagnostic evaluation (e.g. chest x-ray, bone scan, CT scan, or MRI), who are at high-risk for pelvic lymph node metastases  
• A diagnostic imaging agent in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease |
| 10 Indium-111 chloride | Coviden | – | Indicated for radiolabeling:  
• ProstaScint® used for in vivo diagnostic imaging procedures |
| 11 Indium-111 pentetate | GE Healthcare | – | For use in radionuclide cisternography |
| 12 Indium-111 oxyquinoline | GE Healthcare | – | Indicated for radiolabeling autologous leukocytes which may be used as an adjunct in the detection of inflammatory processes to which leukocytes migrate, such as those associated with abscesses or other infection |
| 13 Indium-111 pentetreotide | Coviden | Octreoscan™ | An agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors |
| 14 Iodine I-123 iobenguane | GE Healthcare | AdreView™ | Indicated for use in the detection of primary or metastatic pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests. Indicated for scintigraphic assessment of sympathetic innervation of the myocardium by measurement of the heart to mediastinum (H/M) ratio of radioactivity uptake in patients with New York Heart Association (NYHA) class II or class III heart failure and left ventricular ejection fraction (LVEF) ≤ 35%. Among these patients, it may be used to help identify patients with lower one and two year mortality risks, as indicated by an H/M ratio ≥ 1.6. Limitations of Use: In patients with congestive heart failure, its utility has not been established for: selecting a therapeutic intervention or for monitoring the response to therapy; using the H/M ratio to identify a patient with a high risk for death. |
| 15 Iodine I-123 ioflupane² | GE Healthcare | DaTscan™ | Indicated for striatal dopamine transporter visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS) in whom it may help differentiate essential tremor due to PS (idiopathic Parkinson’s disease, multiple system atrophy and progressive supranuclear palsy) |

Note: See page six for footnotes
<table>
<thead>
<tr>
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<th>Trade Names</th>
<th>Approved Indications in Adults (Pediatric use as noted)</th>
</tr>
</thead>
</table>
| Iodine I-123        | Cardinal Health       | –           | Indicated for use in the evaluation of thyroid:  
• Function  
• Morphology                                                                                                                                                                                        |
| sodium iodide       | Covidien              | –           |                                                                                                                                                                                                                                                                 |
| capsules            |                       |             |                                                                                                                                                                                                                                                                 |
| Iodine I-125        | IsoTex Diagnostics    | Jeanatope   | Indicated for use in the determination of:  
• Total blood  
• Plasma volume                                                                                                                                                                                    |
| human serum albumin |                       |             |                                                                                                                                                                                                                                                                 |
| Iodine I-125        | IsoTex Diagnostics    | Glofil-125  | Indicated for evaluation of glomerular filtration                                                                                                                                                     |
| iothalamate         |                       |             |                                                                                                                                                                                                                                                                 |
| Iodine I-131        | IsoTex Diagnostics    | Megatope    | Indicated for use in determinations of:  
• Total blood and plasma volumes  
• Cardiac output  
• Cardiac and pulmonary blood volumes and circulation times  
• Protein turnover studies  
• Heart and great vessel delineation  
• Localization of the placenta  
• Localization of cerebral neoplasms |
| human serum albumin |                       |             |                                                                                                                                                                                                                                                                 |
| Iodine I-131        | Covidien              | –           | Diagnostic:  
• Performance of the radioactive iodide (RAI) uptake test to evaluate thyroid function  
• Localizing metastases associated with thyroid malignancies  
Therapeutic:  
• Treatment of hyperthyroidism  
• Treatment of carcinoma of the thyroid |
| sodium iodide       | DRAXIMAGE             | HiCON™      | Generation of Tc-99m sodium pertechnetate for administration or radiopharmaceutical preparation                                                                                                                                                                     |
| Mo-99 generator     | GE Healthcare         | DRYTEC™     |                                                                                                                                                                                                                                                                 |
| Molybdenum          | Lantheus Medical      | Technelite® |                                                                                                                                                                                                                                                                 |
| Nitrogen-13         | Various               | –           | Indicated for diagnostic Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease |
| ammonia             |                       |             |                                                                                                                                                                                                                                                                 |
| Radium-223 dichloride| Bayer HealthCare      | Xofigo*     | Indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease                                                                                                                                 |
| Pharmaceuticals Inc.|                       |             |                                                                                                                                                                                                                                                                 |
| Rubidium-82 chloride| Bracco Diagnostics    | Cardiogen-82™| PET myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction                                                                                                             |
| Samarium-153        | Lantheus Medical      | Quadramet®  | Indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on radionuclide bone scan                                                                                                                                 |
| lexidronam          | Imaging               |             |                                                                                                                                                                                                                                                                 |
| Package Inserts may be viewed at [http://nps.cardinal.com/MSDSPI/Main.aspx](http://nps.cardinal.com/MSDSPI/Main.aspx)
<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Manufacturer</th>
<th>Trade Names</th>
<th>Approved Indications in Adults (Pediatric use as noted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 Strontium-89 chloride</td>
<td>GE Healthcare</td>
<td>Metastron™</td>
<td>Indicated for the relief of bone pain in patients with painful skeletal metastases that have been confirmed prior to therapy</td>
</tr>
<tr>
<td>27 Technetium-99m bicine</td>
<td>Lantheus Medical imaging</td>
<td>Neurolite*</td>
<td>SPECT imaging as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed</td>
</tr>
<tr>
<td>28 Technetium-99m disofenin</td>
<td>Pharmalucence</td>
<td>Hepatolite*</td>
<td>Diagnosis of acute cholecystitis as well as to rule out the occurrence of acute cholecystitis in suspected patients with right upper quadrant pain, fever, jaundice, right upper quadrant tenderness and mass or rebound tenderness, but not limited to these signs and symptoms</td>
</tr>
<tr>
<td>29 Technetium-99m exametazine</td>
<td>GE Healthcare</td>
<td>Ceretec™</td>
<td>• As an adjunct in the detection of altered regional cerebral perfusion in stroke</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Leukocyte labeled scintigraphy as an adjunct in the localization of intra abdominal infection and inflammatory bowel disease</td>
</tr>
<tr>
<td>30 Technetium-99m macroaggregated albumin</td>
<td>DRAXIMAGE</td>
<td>–</td>
<td>• An adjunct in the evaluation of pulmonary perfusion (adult and pediatric)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Evaluation of peritoneo-venous (LaVeen) shunt patency</td>
</tr>
<tr>
<td>31 Technetium-99m mebrofenin</td>
<td>Bracco Diagnostics</td>
<td>Choletec®</td>
<td>As a hepatobiliary imaging agent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>As a hepatobiliary imaging agent</td>
</tr>
<tr>
<td>32 Technetium-99m medronate</td>
<td>Bracco Diagnostics</td>
<td>MDP-Bracco™</td>
<td>As a bone imaging agent to delineate areas of altered osteogenesis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>DRAXIMAGE –</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MDP-25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>GE Healthcare MDP Multidose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pharmalucence –</td>
</tr>
<tr>
<td>33 Technetium-99m mertiatide</td>
<td>Covidien</td>
<td>Technescan MAG3™</td>
<td>In patients &gt; 30 days of age as a renal imaging agent for use in the diagnosis of:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Congenital and acquired abnormalities</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Renal failure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Urinary tract obstruction and calculi</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Diagnostic aid in providing:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Renal function</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Split function</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Renal angiograms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Renogram curves for whole kidney and renal cortex</td>
</tr>
<tr>
<td>34 Technetium-99m oxidronate</td>
<td>Covidien</td>
<td>Technescan™ HDP</td>
<td>As a bone imaging agent to delineate areas of altered osteogenesis (adult and pediatric use)</td>
</tr>
<tr>
<td>35 Technetium-99m pentetate</td>
<td>DRAXIMAGE</td>
<td>–</td>
<td>• Brain imaging</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Kidney imaging:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- To assess renal perfusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- To estimate glomerular filtration rate</td>
</tr>
</tbody>
</table>

Package Inserts may be viewed at http://nps.cardinal.com/MSDSPI/Main.aspx
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<th>Approved Indications in Adults (Pediatric use as noted)</th>
</tr>
</thead>
</table>
| 36 Technetium-99m pyrophosphate | Covidien | Technescan™ PYP™ | • As a bone imaging agent to delineate areas of altered osteogenesis  
• As a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction  
• As a blood pool imaging agent useful for:  
  - Gated blood pool imaging  
  - Detection of sites of gastrointestinal bleeding |
| Pharmalucence | – | \_ |
| 37 Technetium-99m red blood cells | Covidien | UltraTag™ | Tc99m-labeled red blood cells are used for:  
• Blood pool imaging including cardiac first pass and gated equilibrium imaging  
• Detection of sites of gastrointestinal bleeding |
| 38 Technetium-99m sestamibi | Cardinal Health | – | Myocardial perfusion agent that is indicated for:  
• Detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects)  
• Evaluating myocardial function  
• Developing information for use in patient management decisions  
• Planar breast imaging as a second line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass |
| Covidien | – | \_ |
| DRAXIMAGE | – | \_ |
| Lantheus Medical Imaging | Cardiolite* | \_ |
| Pharmalucence | – | \_ |
| 39 Technetium-99m sodium pertechnetate | Covidien | – | • Brain Imaging (including cerebral radionuclide angiography)*  
• Thyroid Imaging*  
• Salivary Gland Imaging  
• Placenta Localization  
• Blood Pool Imaging (including radionuclide angiography)*  
• Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux*  
• Nasolacrimal Drainage System Imaging  
(*adult and pediatric use) |
| GE Healthcare | – | \_ |
| Lantheus Medical Imaging | – | \_ |
| 40 Technetium-99m succimer | GE Healthcare | – | An aid in the scintigraphic evaluation of renal parenchymal disorders |
| 41 Technetium-99m sulfur colloid | Pharmalucence | – | • Imaging areas of functioning reticuloendothelial cells in the liver, spleen and bone marrow*  
• It is used orally for:  
  - Esophageal transit studies*  
  - Gastroesophageal reflux scintigraphy*  
  - Detection of pulmonary aspiration of gastric contents*  
• Aid in the evaluation of peritoneo-venous (LeVeen) shunt patency  
• To assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or malignant melanoma when used with a hand-held gamma counter  
(*adult and pediatric use) |
| 42 Technetium-99m tetrofosmin | GE Healthcare | Myoview™ | Myocardial perfusion agent that is indicated for:  
• Detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects)  
• The assessment of left ventricular function (left ventricular ejection fraction and wall motion) |

Package Inserts may be viewed at http://nps.cardinal.com/MSDSPI/Main.aspx
Subsequent to promulgation of 21 C.F.R. Part 212, Current Good Manufacturing Practices (cGMP) for PET Radiopharmaceuticals, firms manufacturing and distributing this drug are required to submit either a NDA or an ANDA by June 12, 2012 and manufacture following cGMP Part 212 regulations as of December 11, 2011 for its continued distribution and sale.

This is a Schedule II controlled substance under the Controlled Substances Act. A DEA license is required for handling or administering this controlled substance.

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<table>
<thead>
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<th>Manufacturer</th>
<th>Trade Names</th>
<th>Approved Indications in Adults (Pediatric use as noted)</th>
</tr>
</thead>
</table>
| 43 Technetium-99m  | Navidea Biopharmaceuticals, Inc. | Lymphoseek* | Indicated with or without scintigraphic imaging for:  
• Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.  
• Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma. |
| 44 Thallium-201 chloride | Covidien | – |  
• Useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction  
• As an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease)  
• Localization of sites of parathyroid hyperactivity in patients with elevated serum calcium and parathyroid hormone levels |
| 45 Xenon-133 gas | Lantheus Medical Imaging | – |  
• The evaluation of pulmonary function and for imaging the lungs  
• Assessment of cerebral flow |
| 46 Yttrium-90 chloride | MDS Nordion | – |  
• Indicated for radiolabeling:  
  • Zevalin* used for radioimmunotherapy procedures |
| 47 Yttrium-90 ibritumomab tiuxetan | Spectrum Pharmaceuticals | Zevalin* |  
• Indicated for the:  
  • Treatment of relapsed or refractory, low-grade or follicular B-cell non-Hodgkin’s lymphoma (NHL)  
  • Treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy |

Package Inserts may be viewed at http://nps.cardinal.com/MSDSPI/Main.aspx

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Ammonia N-13 Injection, USP is a radioactive diagnostic agent for Positron Emission Tomography (PET) indicated for diagnostic PET imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease (1).

**INDICATIONS AND USAGE**

Ammonia N-13 Injection, USP is indicated for diagnostic Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease.

**DOSE AND ADMINISTRATION**

2.1 Rest Imaging Study
- Aseptically withdraw Ammonia N-13 Injection, USP from its container and administer (10-20 mCi (0.368 – 0.736 GBq) as a bolus through a catheter inserted into a large peripheral vein.
- Start imaging 3 minutes after the injection and acquire images for a total of 10-20 minutes.

2.2 Stress Imaging Study
- If a rest imaging study is performed, begin the stress imaging study 40 minutes or more after the first Ammonia N-13 Injection, USP to allow sufficient isotope decay.
- Administer a pharmacologic stress-inducing drug in accordance with its labeling.
- Aseptically withdraw Ammonia N-13 Injection, USP from its container and administer (10-20 mCi (0.368 – 0.736 GBq) of Amnomia N-13 Injection, USP as a bolus at 8 minutes after the administration of the pharmacologic stress-inducing drug.
- Start imaging 3 minutes after the Amnomia N-13 Injection, USP and acquire images for a total of 10-20 minutes.

2.3 Patient Preparation
- To increase renal clearance of radioactivity and to minimize radiation dose to the bladder, hydrate the patient before the procedure and encourage voiding as soon as each image acquisition is completed and as often as possible thereafter for at least one hour.
- To report SUSPECTED ADVERSE REACTIONS, contact Cardinal Health at 1-800-539-1503 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**WARNINGs AND PRECAUTIONS**

- Ammonia N-13 Injection, USP may increase the risk of cancer. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker.

2.4 Radiation Dosimetry
- Glass vial containing 0.138-1.387 GBq (3.75-3.75 mCi/mL) of Amnomia N-13 Injection, USP in aqueous 0.9 % sodium chloride solution (approximately 8 ml volume) (3).

**CONTRAINDICATIONS**

None

2.5 Drug Handling
- Wear waterproof gloves and effective shielding when handling Ammonia N-13 Injection, USP.

**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE

Amnomia N-13 Injection, USP is a radioactive diagnostic agent for Positron Emission Tomography (PET) indicated for diagnostic PET imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease (1).

2 DOSE AND ADMINISTRATION

2.1 Rest Imaging Study
- Aseptically withdraw Amnomia N-13 Injection, USP from its container and administer (10-20 mCi (0.368 – 0.736 GBq) as a bolus through a catheter inserted into a large peripheral vein.
- Start imaging 3 minutes after the injection and acquire images for a total of 10-20 minutes.

2.2 Stress Imaging Study
- If a rest imaging study is performed, begin the stress imaging study 40 minutes or more after the first Amnomia N-13 Injection, USP to allow sufficient isotope decay.
- Administer a pharmacologic stress-inducing drug in accordance with its labeling.
- Aseptically withdraw Amnomia N-13 Injection, USP from its container and administer (10-20 mCi (0.368 – 0.736 GBq) of Amnomia N-13 Injection, USP as a bolus at 8 minutes after the administration of the pharmacologic stress-inducing drug.
- Start imaging 3 minutes after the Amnomia N-13 Injection, USP and acquire images for a total of 10-20 minutes.

2.3 Patient Preparation
- To increase renal clearance of radioactivity and to minimize radiation dose to the bladder, hydrate the patient before the procedure and encourage voiding as soon as each image acquisition is completed and as often as possible thereafter for at least one hour.
- To report SUSPECTED ADVERSE REACTIONS, contact Cardinal Health at 1-800-539-1503 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**CONTRAINDICATIONS**

None

2.4 Radiation Dosimetry
- Glass vial containing 0.138-1.387 GBq (3.75-3.75 mCi/mL) of Amnomia N-13 Injection, USP in aqueous 0.9 % sodium chloride solution (approximately 8 ml volume) (3).

**CONTRAINDICATIONS**

None

**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE

Amnomia N-13 Injection, USP is a radioactive diagnostic agent for Positron Emission Tomography (PET) indicated for diagnostic PET imaging of the myocardium under rest or pharmacologic stress conditions to evaluate myocardial perfusion in patients with suspected or existing coronary artery disease (1).

2 DOSE AND ADMINISTRATION

2.1 Rest Imaging Study
- Aseptically withdraw Amnomia N-13 Injection, USP from its container and administer (10-20 mCi (0.368 – 0.736 GBq) as a bolus through a catheter inserted into a large peripheral vein.
- Start imaging 3 minutes after the injection and acquire images for a total of 10-20 minutes.

2.2 Stress Imaging Study
- If a rest imaging study is performed, begin the stress imaging study 40 minutes or more after the first Amnomia N-13 Injection, USP to allow sufficient isotope decay.
- Administer a pharmacologic stress-inducing drug in accordance with its labeling.
- Aseptically withdraw Amnomia N-13 Injection, USP from its container and administer (10-20 mCi (0.368 – 0.736 GBq) of Amnomia N-13 Injection, USP as a bolus at 8 minutes after the administration of the pharmacologic stress-inducing drug.
- Start imaging 3 minutes after the Amnomia N-13 Injection, USP and acquire images for a total of 10-20 minutes.

2.3 Patient Preparation
- To increase renal clearance of radioactivity and to minimize radiation dose to the bladder, hydrate the patient before the procedure and encourage voiding as soon as each image acquisition is completed and as often as possible thereafter for at least one hour.
- To report SUSPECTED ADVERSE REACTIONS, contact Cardinal Health at 1-800-539-1503 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**CONTRAINDICATIONS**

None

2.4 Radiation Dosimetry
- Glass vial containing 0.138-1.387 GBq (3.75-3.75 mCi/mL) of Amnomia N-13 Injection, USP in aqueous 0.9 % sodium chloride solution (approximately 8 ml volume) (3).

**CONTRAINDICATIONS**

None

3 DOSAGE FORMS AND STRENGTHS

Glass vial (10 mL) containing 0.138-1.387 GBq (3.75-3.75 mCi/mL) of Amnomia N-13 Injection, USP in aqueous 0.9 % sodium chloride solution (approximately 8 mL volume) that is suitable for intravenous administration.

**4 CONTRAINDICATIONS**

None

**ADVERSE REACTIONS**

No adverse reactions have been reported for Amnomia N-13 Injection, USP based on a review of the published literature, publicly available reference sources, and adverse drug reaction reporting system (6).

**USE IN SPECIFIC POPULATIONS**

It is not known whether this drug is excreted in human milk. Alternatives to breastfeeding (e.g. using stored breast milk or infant formula) should be used for 2 hours (<10 half-lives of radioactive decay for N-13 isotope) after administration of Amnomia N-13 Injection, USP (8.3).

The safety and effectiveness of Amnomia N-13 Injection, USP has been established in pediatric patients (8.4).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 06/2013

Table 1: N-13 Absorbed Radiation Dose Per Unit Activity (rem/mCi) for Adults and Pediatric Groups

<table>
<thead>
<tr>
<th>Organ</th>
<th>Adult</th>
<th>15-year old</th>
<th>10-year old</th>
<th>5-year old</th>
<th>1-year old</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenals</td>
<td>0.0055</td>
<td>0.0096</td>
<td>0.016</td>
<td>0.025</td>
<td>0.048</td>
</tr>
<tr>
<td>Brain</td>
<td>0.016</td>
<td>0.016</td>
<td>0.017</td>
<td>0.019</td>
<td>0.027</td>
</tr>
<tr>
<td>Breast</td>
<td>0.0067</td>
<td>0.0067</td>
<td>0.010</td>
<td>0.017</td>
<td>0.035</td>
</tr>
<tr>
<td>Stomach wall</td>
<td>0.0063</td>
<td>0.0078</td>
<td>0.012</td>
<td>0.019</td>
<td>0.037</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.0067</td>
<td>0.0081</td>
<td>0.003</td>
<td>0.021</td>
<td>0.041</td>
</tr>
</tbody>
</table>

**5 WARNINGS AND PRECAUTIONS**

- It is not known whether this drug is excreted in human milk. Alternatives to breastfeeding (e.g. using stored breast milk or infant formula) should be used for 2 hours (<10 half-lives of radioactive decay for N-13 isotope) after administration of Amnomia N-13 Injection, USP (8.3).

**11 DESCRIPTION**

1.1 Chemical Characteristics
1.2 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**

**15 REFERENCES**

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

17.1 Pre-study Hydration
17.2 Post-study Voiding
17.3 Post-study Breastfeeding Avoidance

**17.3 Post-study Breastfeeding Avoidance**

- It is not known whether this drug is excreted in human milk. Alternatives to breastfeeding (e.g. using stored breast milk or infant formula) should be used for 2 hours (<10 half-lives of radioactive decay for N-13 isotope) after administration of Amnomia N-13 Injection, USP (8.3).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 06/2013
Ammonia N-13 Injection, USP may increase the risk of cancer. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker [see Dosage and Administration (2.4)].

6. ADVERSE REACTIONS

No adverse reactions have been reported for Ammonia N-13 Injection, USP based on a review of the published literature, publicly available reference sources, and adverse drug reaction reporting systems. However, the completeness of these sources is not known.

7. DRUG INTERACTIONS

The possibility of interactions of Ammonia N-13 Injection, USP with other drugs taken by patients undergoing PET imaging has not been studied.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with Ammonia N-13 Injection, USP. It is also not known whether Ammonia N-13 Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ammonia N-13 Injection, USP should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for radiation exposure to nursing infants from Ammonia N-13 Injection, USP, use alternative infant nutrition sources (e.g., stored breast milk or infant formula) for 2 hours (>10 half-lives of radioactive decay for N-13 isotopic) after administration of the drug or avoid use of the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

The safety and effectiveness of Ammonia N-13 Injection, USP has been established in pediatric patients based on known metabolism of ammonia, radiation dosimetry in the pediatric population, and clinical studies in adults [see Dosage and Administration (2.4)].

11 DESCRIPTION

11.1 Chemical Characteristics

Ammonia N-13 Injection, USP is a positron emitting radiopharmaceutical that is used for diagnostic purposes in conjunction with position emission tomography (PET) imaging. The active ingredient, [13N] ammonia, has the molecular formula of NH3 with a molecular weight of 18.02, and has the following chemical structure:

Ammonia N-13 Injection, USP is provided as a ready to use sterile, pyrogen-free, clear solution. Each mL of the solution contains between 1.11–11.1 GBq (30–300 mCi/mL) of [13N] ammonia, at the end of synthesis (EOS) reference time, in 0.9% aqueous sodium chloride. The pH of the solution is between 4.5 to 7.5. The recommended dose of radioactivity (10-20 mCi) is associated with a theoretical mass dose of 0.5-1.0 pCi/mmol of ammonia.

12.1 Mechanism of Action

Ammonia N-13 Injection, USP is a radiolabeled analog of ammonia that is distributed to all organs of the body after intravenous administration. It is extracted from the blood in the coronary capillaries into the myocardial cells where it is metabolized to glutamine-N-13 and retained in the cells. The presence of ammonia N-13 and glutamine N-13 in the myocardium allows for PET imaging of the myocardium.

12.2 Pharmacodynamics

Following intravenous injection, ammonia N-13 enters the myocardium through the coronary arteries. The PET technique measures myocardial blood flow based on the assumption of a three-compartmental disposition of intravenous ammonia N-13 in the myocardium. In this model, the value of the rate constant, which represents the delivery of blood to myocardium, and the fraction of ammonia N-13 extracted into the myocardial cells, is a measure of myocardial blood flow. Optimal PET imaging of the myocardium is generally achieved between 10 to 20 minutes after administration.

12.3 Pharmacokinetics

Following intravenous injection, Ammonia N-13 Injection, USP is cleared from the blood with a biologic half-life of about 2.84 minutes (effective half-life of about 2.21 minutes). In the myocardium, its biologic half-life has been estimated to be less than 2 minutes (effective half-life less than 1.67 minutes).

The mass dose of Ammonia N-13 Injection, USP is very small as compared to the normal range of ammonia in the blood (0.72-3.30 mg) in a healthy adult man [see Description (11.1)].

Plasma protein binding of ammonia N-13 or its N-13 metabolites has not been studied. Ammonia N-13 undergoes a five-enzyme step metabolism in the liver to yield urea N-13 (the main circulating metabolite). It is also metabolized to glutamine N-13 (the main metabolite in tissues) by glutamine synthetase in the skeletal muscles, liver, brain, myocardium, and other organs. Other metabolites of ammonia N-13 include small amounts of N-13 amino acid anions (acidic amino acids) in the forms of glutamate N-13 or aspartate N-13.

Ammonia N-13 is eliminated from the body by urinary excretion mainly as urea N-13. The pharmacokinetics of Ammonia N-13 Injection, USP have not been studied in renal impaired, hepatically impaired, or pediatric patients.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies have not been performed to evaluate the carcinogenic potential of Ammonia N-13 Injection, USP. Genotoxicity assays and impairment of male and female fertility studies with Ammonia N-13 Injection, USP have not been performed.

14 CLINICAL STUDIES

In a descriptive, prospective, blinded image interpretation study of adult patients with known or suspected coronary artery disease, myocardial perfusion deficits in stress and rest PET images obtained with Ammonia N-13 (N=111) or Rubidium 82 (N=82) were compared to changes in stenosis flow reserve (SFR) as determined by coronary angiography. The principal outcome of the study was the evaluation of PET defect severity relative to SFR. PET perfusion defects at rest and stress in seven cardiac regions (anterior, apical, anteroseptal, posteroseptal, anterolateral, posterolateral, and inferior walls) were graded on a 0 to 3 scale defined as normal (0), possible (1), probable (2), mild (3), moderate (4), and severe (5) defects. Coronary angiograms were used to measure absolute and relative stenosis dimensions and to calculate stenosis flow reserve defined as the maximum value of flow at maximum coronary vasodilatation relative to rest flow under standardized hemodynamic conditions. SFR scores ranged from 0 (total occlusion) to 5 (normal). With increasing impairment of flow reserve, the subjective PET defect severity increased. A PET defect score of 2 or higher was positively correlated with flow reserve impairment (SFR<0.4).

15 REFERENCES


16 HOW SUPPLIED/STORAGE AND HANDLING

Ammonia N-13 Injection, USP is packaged in 10 mL multiple dose glass vials containing between 1.11-11.1 GBq (30-300 mCi/mL) of [13N] ammonia, at the end of synthesis (EOS) reference time, in 0.9% sodium chloride injection solution in approximately 8 mL volume. The recommended dose of radioactivity (10-20 mCi) is associated with a theoretical mass dose of 0.5-1.0 pCi/mmol of Ammonia.

NDC: 65857-200-10

Storage

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Use the solution within 60 minutes of the End of Synthesis (EOS) calibration.

17 PATIENT COUNSELING INFORMATION

17.1 Pre-study Hydration

Instruct patients to drink plenty of water or other fluids (as tolerated) in the 4 hours before their PET study.

17.2 Post-study Voiding

Instruct patients to void after completion of each image acquisition session and as often as possible for one hour after the PET scan ends.

17.3 Post-study Breastfeeding Avoidance

Instruct nursing patients to store breast milk in airtight containers for breast milk for 2 hours after administration of Ammonia N-13 Injection, USP.

Manufactured by:

Cardinal Health 414, LLC
7000 Cardinal Place
Dublin, OH 43017

Distributed by:

Cardinal Health 414, LLC
7000 Cardinal Place
Dublin, OH 43017

Revised: 06/2013
10. DESCRIPTIVE

Each patient underwent a 60-minute, non-geriatric, standardized motion test.

- Treadmill Test (Toddler/Toddler 2, 3-5 years old) - 1.5 m
- Treadmill Test (Junior/Toddler 6-8 years old) - 1.5 m
- Cycle Ergometer Test (Junior/Toddler 6-8 years old) - 1 m
- Cycle Ergometer Test (Adult/Toddler 9-10 years old) - 1 m
- Cycle Ergometer Test (Adult/Toddler 11-12 years old) - 1 m

Prior to the treadmill, the participants rested for 5 to 10 minutes. The test was supervised at all times.

This protocol was administered in admittance for diagnostic use after reconditioning with rest and reconditioning for future Treadmill Testing. The test is performed in the protocol described in 10.1.2.1. All technical specifications are present.

The purpose of this investigation was to assess the efficacy of Treadmill Testing and the suitability of the test results for guiding rehabilitation.

The precision of the test is ±0.5 m²/km.

The data collected from this investigation was used to assess the efficacy of Treadmill Testing and the suitability of the test results for guiding rehabilitation.

If there is a need for additional information, please contact the author for further clarification.

9. CONCLUSION

The Treadmill Test is a valid and reliable method for assessing the physical fitness of children and adolescents.

The Treadmill Test has been shown to be a valid and reliable method for assessing the physical fitness of children and adolescents.

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Sodium Iodide I 123
Diagnostic-Capsules for Oral Administration

DESCRIPTION
Sodium Iodide I 123 (Na<sup>123</sup>I) for diagnostic use is supplied in capsules for oral administration. The capsules are available in strengths of 3.7, 7.4 and 14.8 megabecquerels (MBq) (100, 200 and 400 μCi) I 123 at time of calibration.

The radionuclidic composition at calibration is not less than 97.0 percent I 123, not more than 2.9 percent I 125 and not more than 0.1 percent all others (I 121 or Te 121.) The radionuclidic composition at expiration time is not less than 87.2 percent I 123, not more than 12.4 percent I 125 and not more than 0.4 percent all others. The ratio of the concentration of I 123 and I 125 changes with time. Graph 1 shows the maximum concentration of each as a function of time.

![Graph 1](image)

Radionuclidic Concentration of I 123 and I 125

PHYSICAL CHARACTERISTICS
Sodium iodide I 123 decays by electron capture with a physical half-life of 13.2 hours. The photon that is useful for detection and imaging studies is listed in Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean % Disintegration</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>83.4</td>
<td>159</td>
</tr>
</tbody>
</table>

Kocher, David C., Radioactive Decay Data Tables, DOE/TIC-11026, 122, (1981)

EXTERNAL RADIATION
The specific gamma ray constant for I 123 is 1.6×10<sup>-9</sup> rad/hr·mCi at 1 cm. The first half-value thickness of lead (Pb) for I 123 is 0.005 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 1.63 cm of lead will decrease the external radiation exposure by a factor of about 1.00.

### Table 2

<table>
<thead>
<tr>
<th>Shield Thickness (Pb), cm.</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.036</td>
<td>0.5</td>
</tr>
<tr>
<td>0.120</td>
<td>10&lt;sup&gt;-1&lt;/sup&gt;</td>
</tr>
<tr>
<td>0.240</td>
<td>10&lt;sup&gt;-2&lt;/sup&gt;</td>
</tr>
<tr>
<td>0.358</td>
<td>10&lt;sup&gt;-3&lt;/sup&gt;</td>
</tr>
<tr>
<td>0.477</td>
<td>10&lt;sup&gt;-4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>


Note that these estimates of attenuation do not take into consideration the presence of contaminants.

To correct for physical decay of I 123, the fractions that remain at selected intervals after the time of calibration are shown in Table 3.

### Table 3

<table>
<thead>
<tr>
<th>Sodium Iodide I 123 Decay Chart: Half-Life 13.2 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>12</td>
</tr>
<tr>
<td>15</td>
</tr>
</tbody>
</table>

*Time of Calibration

CLINICAL PHARMACOLOGY
Sodium Iodide I 123 is readily absorbed from the upper gastrointestinal tract. Following absorption, the iodide is distributed primarily within the extracellular fluid of the body. It is trapped and organically bound by the thyroid and concentrated by the stomach, choroid plexus and salivary glands. It is excreted by the kidneys.

The fraction of the administered dose which is accumulated in the thyroid gland may be a measure of thyroid function in the absence of unusually high or low iodine intake or administration of certain drugs which influence iodine accumulation by the thyroid gland. Accordingly, the patient should be questioned carefully regarding previous medication and/or procedures involving radiographic media. Normal subjects can accumulate approximately 10-50% of the administered iodine dose in the thyroid gland, however, the normal and abnormal ranges are established by individual physician's criteria. The mapping (imaging) of Sodium iodide I 123 distribution in the thyroid gland may provide useful information concerning thyroid anatomy and definition of normal and/or abnormal functioning of tissue within the gland.

INDICATION AND USE
Administration of Sodium Iodide I 123 is indicated as a diagnostic procedure to be used in evaluating thyroid function and/or morphology.

CONTRAINDICATIONS
To date there are no known contraindications to the use of Sodium Iodide I 123 capsules.

WARNINGS
Females of childbearing age and children under 18 should not be studied unless the benefits anticipated from the performance of the test outweigh the possible risk of exposure to the amount of ionizing radiation associated with the test.
PRECAUTIONS

General
The contents of the capsule are radioactive. Adequate shielding of the preparation must be maintained at all times.

Do not use after the expiration time and date (30 hours after calibration time) stated on the label.

The prescribed Sodium Iodide 123 dose should be administered as soon as practical from the time of receipt of product (i.e., as close to calibration time as possible) in order to minimize the fraction of radiation exposure due to relative increase of radionuclidic contaminants with time.

Sodium Iodide 123, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in their safe use and handling of radionuclides 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 potential, mutagenic potential, or whether Sodium Iodide 123 affects fertility in males or females.

Pregnancy Category C
Animal reproduction studies have not been conducted with this drug. It is also not known whether Sodium Iodide 123 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Iodide 123 should be given to a pregnant woman only if clearly needed.

Ideally examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately ten) days following the onset of menses.

Nursing Mothers
Since I 123 is excreted in human milk, formula-feeding should be substituted for breast-feeding if the agent must be administered to the mother during lactation.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Although rare, reactions associated with the administration of Sodium Iodide isotopes for diagnostic use include, in decreasing order of frequency, nausea, vomiting, chest pain, tachycardia, itching skin, rash and hives.

RADIATION DOSIMETRY
The estimated absorbed radiation doses to several organs of an average patient (70 kg) from oral administration of the maximum dose of 14.8 MBq (400 uCi) of I 123 are shown in Table 4 for thyroid uptakes of 5, 15, and 25%.

For comparison at these three values of thyroid uptake, the estimated radiation doses from doses of 3.7 MBq (100 uCi) I 131, also used as thyroid imaging agent, are also included.

Table 4

<table>
<thead>
<tr>
<th>Organ</th>
<th>I 123 (mGy/14.8 MBq)</th>
<th>I 131 (mGy/3.7 MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(in adults/uCi)</td>
<td>(in adults/uCi)</td>
</tr>
<tr>
<td></td>
<td>TOC</td>
<td>TOC</td>
</tr>
<tr>
<td>Thyroid</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>Liver</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Oxidase</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Red</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Spleen</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td>Small Intest</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>Bladder</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Skeleton</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Butyric Acid</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>20</td>
</tr>
</tbody>
</table>

* Concentration of Time of Caliber: 99% I 123, 2.6% I 131, 0.1% I 131

Concentration of Time of Caliber: 92% I 123, 12.4% I 131, 0.4% I 131

All Iodine Kinetics detected as in MIRD Dose Estimate Report 5, Bladder voiding interval, 1.8 hours.

Tallium 201 dose taken from ICRP 30.

HOW SUPPLIED
Sodium Iodide 123 is supplied as capsules for oral administration in strengths of 3.7 MBq (100 uCi), 7.4 MBq (200 uCi), and 14.8 MBq (400 uCi) at time of calibration. Each gelatin capsule contains 0.45 - 0.55 g of sucrose.

The capsules are packaged in plastic vials containing either one or five capsules of a single strength per vial. The plastic vial is packaged in a lead shield with a label identical to that affixed to the plastic vial. A package insert is supplied with each lead shield.

The -I (iodine) content for a 100 uCi capsule is 5.2 ng the -I content for a 200 uCi capsule is 10.4 ng the -I content for a 400uCi capsule is 20.8 ng at TOC.

Dispense and preserve capsules in well-closed containers that are adequately shielded. Store at room temperature, below 68°F.

The contents of the capsules are radioactive. Adequate shielding and handling precautions must be maintained.

CARDINAL HEALTH

Denver, CO 80011

Sodium Iodide 123

1-020-14

Printed in U.S.A.

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