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A vacancy for a nuclear medicine physicist at the rank of Assistant Professor is expected. Duties include clinical services and teaching. Doctoral degree in medical physics or related disciplines is required. Board certification preferred at time of appointment; required after three years of appointment. Interested persons should send a letter, current curriculum vitae and names of three professional references to: Robert Y. L. Chu, PhD, Acting Director of Medical Physics, Department of Radiological Sciences, University of Oklahoma Health Sciences Center, Post Office Box 26901, Oklahoma City, OK 73190. The University of Oklahoma is an equal opportunity/affirmative action employer.

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Peoria Radiology Associates seeks a board certified radiologist with specialty board certification in nuclear medicine. Responsibilities will include Division Chief of the Nuclear Medicine section and occasional coverage of CT, MRI, Sonography and General Radiology. The successful candidate will be joining a group of 20 radiologists with a thriving practice in a large tertiary care hospital and surrounded by community hospitals. Resident and medical student teaching will be expected. Send CV and date of availability to: Dr. G.T. Campbell, c/o Laura Lee, Peoria Radiology Associates, 530 N.E. Glen Oak Ave., Peoria, IL 61637.

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Just a reminder...
The JNM special issues are available for sale.

May JNM - Cardiology Special Section (available after May 15, 1996)
A special cardiology section will stress the advances in myocardial profusion imaging. Also featured: the latest research in technetium-99m-sestamibi tracers to detect vascular thromboses.

June JNM - Oncology Special Issue (available after June 15, 1996)
Articles in this special issue will emphasize the importance of nuclear medicine in the diagnosis and management of disease and the evaluation of treatments in patients with various cancers. Other articles explore the most recent advances using somatostatin imaging tracers.

July JNM - Neurology Special Issue (available after July 15, 1996)
Special focus articles address the role of FDG-PET in Alzheimer’s and other neurologic diseases, and the use of PET and SPECT in relation to epilepsy. This issue also includes the SNM Brain Imaging Council recommendations for performing brain studies.

To order copies of the JNM special issues, contact Matthews Medical Books at: 800-633-2665 or outside the U.S. call 314-432-1401.

Classified Advertising
Each description of the products below was condensed from information supplied by the manufacturer. The reviews are published as a service to the professionals working in the field of nuclear medicine and their inclusion herein does not in any way imply an endorsement by the Editorial Board of *The Journal of Nuclear Medicine* or by the Society of Nuclear Medicine.

**Macintosh®-based Thyroid Uptake System with Expanded Programs**

Biodex Medical Systems offers a Macintosh®-based thyroid uptake system packaged in the Macintosh and connected to a 1024 Channel Multi-Channel Analyzer. The system, called the Atomlab 950, displays real-time patient data and includes programs for thyroid uptake, wipe testing, bioassay, scilling tests, administration/QA and an expanded hematology mode that includes: GFR and ERPF, RBC survival and blood volume. With 8 mb ram and a 500 mb hard drive, the system has more than enough room to include extra department software. PC only users will appreciate the Power Mac's built-in programs that reads and translates PC files. An example of some of the programs included are: a wipe test program extensive enough to satisfy new regulations and includes the ability to customize site and location document in clear, quality report-style. All program reports are generated on a laser-quality printer on either facility letterhead or standard stationary. The Atomlab 950 can be configured with either a mobile stand for convenient use or as a table top. Set up for departments with limited floorspace. Biodex Medical Systems, Brookhaven R&D Plaza, P.O. Box 702, Shirley, NY 11967-0702. Phone: (800) 224-6339. Fax: (516) 924-9241.

**Toshiba Introduces Triple-Energy Window SPECT for Scatter Correction**

The triple-energy window SPECT is available from Toshiba America Medical Systems' GCA-7000 series nuclear medicine gamma cameras. One of the most significant factors degrading image quality in planar and SPECT studies is Compton scatter. Scattered photons coming from different, but unknown origins mix with true peak photons and contribute to a falsely increased count rate. As a result, organs close to each other are not well-differentiated when imaged. This problem is even more apparent when studies of different organs are conducted within a short time frame or during scans that require the use of high-energy nuclides, said Steve Sickles, manager, nuclear medicine business unit. By isolating and measuring the scattered photons and subtracting that information from the images, clean data can be produced. Three windows, one for the main energy peak and two for scatter measurement (using a scatter estimation and subtraction algorithm) are called the triple energy window scatter correction method. The benefits of this feature are: improved image resolution and increased accuracy of image quantification, resulting in improved diagnostic accuracy. Image quality is also enhanced when radiopharmaceuticals with multiple energy peaks are used. With this scatter correction method, a dual-isotope, single acquisition produces image quality closely resembling that of a dual-isotope, dual-acquisition study. Toshiba America Medical Systems, Inc., Attn: Catherine M. Elits, 2441 Michelle Dr., Tustin, CA 92681-2068. Phone: (714) 669-4140. Fax: (714) 730-4022.

**New CD-Rom Offers Health Science Information from 200 Publishers**

J.A. Majors Company is offering a CD-Rom product, called majors.doc (Majors Database on CD). With the majors.doc CD, users can locate information on health science books and multimedia products from more than 200 publishers. Over 40,000 individual listings are incorporated in the system including titles, authors, price, bibliographic information and table of contents. This CD-Rom will allow the health care practitioner to make better buying decisions and to select more titles that meet their specific needs. In addition, researchers will be able to use majors.doc to review a clinical discipline for existing products in seconds. Information is updated monthly. The publishers currently listed include major health science publishing houses such as Mosby, Lippincott-Raven and McGraw-Hill and professional associations such as American Psychiatric Press and small medical presses like Lexi-Comp and Tarascon will be available. For the novice, majors.doc can search for a key word or allow the user to apply sophisticated searching techniques like Boolean logic to review all fields for focused topics such as pediatric leukemia or dermatologic complications with AIDS patients. The user will be able to store, retrieve, display and print data on the selected titles. J.A. Majors Company, Attn: Carolyn Lewis, P.O. Box 819074, Dallas, TX 75381-9074. Phone: (214) 888-4664. E-mail: clewis@mail.majors.com.

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Attention Picker Nuclear Medicine Product Users

Eclipse Systems, Inc., is a full service company specializing in sales, service, software and consulting for nuclear medicine products including Picker SX series cameras and PCS series computers. We are authorized distributors of MSE software, and we are the originators of Total Eclipse total body imaging software for Picker SX series stands with PCS computers. Eclipse also sells and services other manufacturers' gamma camera systems including ADAC and Toshiba.

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In the interest of providing low-cost continuing education to its membership, the SNM has established a rental program of video tapes recorded live at the Annual Meetings. All of the video tapes in the SNM 1995-1996 Audiovisual catalog are available for rental as well as purchase.

The rental fee of $14.00 per tape or one coupon includes:
- Rental of one video tape for a two-week period.
- Shipping charges to the customer.
- One CME/VOICE evaluation form good for continuing education credit for up to 10 viewers.

Rental of a video tape costs $14.00. Use either the order form on the back of the 1995-1996 Audiovisual catalog or acquire a coupon, worth one free rental, through one of the sponsoring companies. For coupons please contact: Bracco, Dupont, Mallinckrodt, Medi-Physics or Syncor.

If you have questions or need further information about the coupons, please contact the Society of Nuclear Medicine at (703) 708-9000, ext. 250. If you would like to order a video tape, please contact the National Audio Video, Inc. at 1-800-373-2952.

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Iodinated I-125 Albumin Injection

Sensitivity and accuracy are the features that make radiolabelled human serum albumin a well-established diagnostic tool for the determination of total blood and plasma volumes. Jeanatope distributes rapidly and uniformly throughout the intravascular pool so that blood volume determinations can be made within 45 minutes after injection. Unlike classical colorimetric methods, frequent determinations can be made and are unaffected by hemolysis or blood turbidity.

Each multi-dose vial of Megatope or Jeanatope contains approximately 10 mg of protein associated with 1 megabecquerels (1 mCi) of I-131 or I-125, respectively, at the time of manufacture. These products are sterile, non-pyrogenic, and dissolved in phosphate-buffered saline with 0.9% benzyl alcohol as preservative. Complete assay data for each lot are provided on the container.

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With gated stress Cardiolite studies, you simultaneously obtain stress perfusion and resting function (wall motion, wall thickening, and LVEF)—that’s more diagnostic information than perfusion alone, which can help you improve patient management. And, the higher photon energy (140 keV) reduces attenuation and improves image quality.

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Cardiolite
Kit for the preparation of Technetium Tc99m Sestamibi

To reduce the uncertainty Cardiolite comes through

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Cardiolite®
Kit for the preparation of Technetium Tc99m Septa

FOR DIAGNOSTIC USE

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the preparation of Technetium Tc99m Septa, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localization of regional myocardial perfusion defects and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and comparative stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent’s labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

CONTRAINdications: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Septa use and is usually associated with exercise stress testing (see PRECAUTIONS).

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, dyspnea, syncope, bronchospasm, and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent’s labeling.

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Septa and are not to be administered directly to the patient without first undergoing the preparatory procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pentasceptate Tc99m injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pentasceptate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m should be injected into the patient within 6 hours after preparation.

Radiochemicals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiochemicals and whose experience and training have been approved by the appropriate government agency authorized to license the use of radiochemicals.

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate radiation protection and support apparatus. The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Septa studies (two-thirds were cardiac patients) were:

- Fatigue 20%
- Diaphoresis 17%
- Chest Pain 10%
- ST depression 7%
- Arrhythmia 1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other technetium labeled radiochemicals, the radiation dose to the ovaries (1.5 microCi/mCi at rest, 1.2 microCi/mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section).

The active intermediate, [Co(NH3)6]2+BF4, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/GPT, and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (2 microM), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. [Co(NH3)6]2+BF4 did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (1mg/kg, > 600 x minimal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Septa. It is also not known whether Technetium Tc99m Septa can cause fetal harm when administered to a pregnant woman or have reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Septa should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Technetium Tc99m Pentasceptate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Septa is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient paronychia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Septa. A few cases of transient headache, pruritus and rash, urticaria, dry mouth, fever, diarrhea, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS).

The following adverse reactions have been rarely reported: allergic reactions consisting of urticaria occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, and vomiting within two hours after a second injection of Technetium Tc99m Septa.

DOSEAGE AND ADMINISTRATION: The suggested dose range for Tc99m administration in a single dose to be employed in the average patient (70kg) is: 370-1110MBq (10-30mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parasurgical drug products should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit.

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Septa injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Septa

<table>
<thead>
<tr>
<th>Organ</th>
<th>2.0 hour void</th>
<th>4.8 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REST</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ON</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organ</td>
<td>Rad/mCi/mCi</td>
<td>Rad/mCi/mCi</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td>1110MBq</td>
<td>1110MBq</td>
</tr>
<tr>
<td><strong>Brew</strong></td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Upper Large Intestine</td>
<td>5.4</td>
<td>5.4</td>
</tr>
<tr>
<td>Lower Large Intestine</td>
<td>3.9</td>
<td>4.0</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>0.8</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>2.0</td>
<td>4.2</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.5</td>
<td>4.8</td>
</tr>
</tbody>
</table>

| STRESS                  |               |               |
| **ON**                  |               |               |
| **Activity**            | 1110MBq      | 1110MBq      |
| Organ                  | Rad/mCi/mCi | Rad/mCi/mCi |
| **Brew**               | 0.2           | 0.2           |
| Gallbladder Wall        | 2.8           | 2.8           |
| Small Intestine         | 2.4           | 2.4           |
| Upper Large Intestine   | 4.5           | 4.5           |
| Lower Large Intestine   | 3.3           | 3.3           |
| Stomach Wall            | 0.5           | 0.5           |
| Heart Wall              | 0.5           | 0.5           |
| Kidneys                 | 1.7           | 1.7           |
| Liver                   | 0.4           | 0.4           |
| Lungs                   | 0.3           | 0.2           |
| Bone Surfaces           | 0.6           | 0.6           |
| Thyroid                 | 0.3           | 0.2           |
| Testes                  | 1.2           | 1.2           |
| Red Marrow              | 0.5           | 0.5           |
| Urinary Bladder Wall    | 1.5           | 3.0           |
| Total Body              | 0.4           | 4.2           |

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Circle Reader Service Number 34

513121-0296 2/96 Printed in U.S.A.
Technetium Tc99m Tetrofosmin For Injection

so clear...

so flexible!

See brief summary of prescribing information on the following page.
CONTRAINDICATIONS

55.5-74 In None

Myoview management. 185-296 total for contents

Each dose should be administered two hours after injection. Significant hypotension (76%)

Myoview. It is not known whether Myoview can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Therefore, Myoview should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Technetium Tc99m Pertechnetate can be excreted in human milk. Therefore, formula should be substituted for breast milk until the technetium has cleared from the body of the nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 784 adults (511 men and 253 women) with a mean age of 56.7 years (range 26-94 years). The subjects received a mean dose of 7.67 MBq on the first injection and 22.4 MBq on the second injection of Myoview.

Deaths did not occur during the clinical study period of 2 days. Six cardiac deaths occurred 3 days to 6 months after injection and were thought to be related to the underlying disease or cardiac surgery. After Myoview injection, serious episodes of angina occurred in 3 patients. Overall cardiac adverse events occurred in 5/784 (less than 1 %) of patients after Myoview injection.

The following events were noted in less than 1 % of patients:

Cardiovascular: angina, hypotension, Torsades de Pointes
Gastrointestinal: vomiting, dyspepsia
Hypersensitivity: cutaneous allergy, hypotension, dyspnea
Special Senses: metallic taste, burning of the mouth, smelling something

There was a low incidence (less than 4%) of a transient and clinically insignificant rise in white blood cell counts following administration of the agent.

DOSAGE AND ADMINISTRATION

For exercise and rest imaging, Myoview is administered in two doses:

• The first dose of 5-6 MBq (185-296 MBq) is given at peak exercise.
• The second dose of 15-24 MBq (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in nonly or liver impaired, pediatric or geriatric patients.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in Table 1. The values are listed in descending order as rad/mCi and Sv/MBq and assume urinary bladder emptying at 3.5 hours.

Table 1

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Exercise</th>
<th>Rest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rad/mCi</td>
<td>µSv/MBq</td>
</tr>
<tr>
<td>Gall blader wall</td>
<td>0.123</td>
<td>33.2</td>
</tr>
<tr>
<td>Upper large intestine</td>
<td>0.075</td>
<td>20.1</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>0.068</td>
<td>15.5</td>
</tr>
<tr>
<td>Lower large intestine</td>
<td>0.057</td>
<td>15.3</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.045</td>
<td>12.1</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.039</td>
<td>10.4</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.030</td>
<td>8.04</td>
</tr>
<tr>
<td>Ovary</td>
<td>0.009</td>
<td>7.86</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.027</td>
<td>7.34</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.023</td>
<td>6.23</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.019</td>
<td>5.00</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.017</td>
<td>4.60</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.016</td>
<td>4.34</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.016</td>
<td>4.32</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>4.14</td>
</tr>
<tr>
<td>Red marrow</td>
<td>0.015</td>
<td>4.14</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.015</td>
<td>4.12</td>
</tr>
<tr>
<td>Muscle</td>
<td>0.013</td>
<td>3.52</td>
</tr>
<tr>
<td>Testes</td>
<td>0.013</td>
<td>3.41</td>
</tr>
<tr>
<td>Liver</td>
<td>0.012</td>
<td>3.22</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.012</td>
<td>3.11</td>
</tr>
<tr>
<td>Brain</td>
<td>0.010</td>
<td>2.72</td>
</tr>
<tr>
<td>Lung</td>
<td>0.008</td>
<td>2.27</td>
</tr>
<tr>
<td>Skin</td>
<td>0.008</td>
<td>2.22</td>
</tr>
<tr>
<td>Breastas</td>
<td>0.008</td>
<td>2.22</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 (rev). Society of Nuclear Medicine, 1976. Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18-[1-4], 1989) for the calculation of dose per mCi and mSv per MBq after exercise and rest respectively.

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Patent No. 5,045,302 (R)

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February, 1996

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- No supplemental exercise necessary

Rapid onset, short duration

- <10-second half-life minimizes post-infusion monitoring time
- Side effects usually resolve quickly

ADENOSCAN®
adenosine

Please see brief summary of prescribing information on adjacent page for warnings, precautions and contraindications.

SINOPSIS

**For Intravenous Infusion Only**

**DESCRIPTION**

Adenoscan® is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-aminono-9-beta-D-ribofuranosyl-6-hydrate.

Adenoscan is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by warming and lowering the pH of the solution.

Each Adenoscan vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/mL and sodium chloride 9 mg/mL. Water for injection, q.s. The pH of the solution is between 4.8 and 7.5.

**INDICATIONS AND USAGE**

Intravenous Adenoscan is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. (See WARNINGS.)

**CONTRAINdications**

Intravenous Adenoscan (adenosine) should not be administered to patients with:

1. Second- or third-degree AV block (except in patients with a functioning artificial pacemaker).
2. Severe bradycardia, such as sick sinus syndrome or symptomatic bradyarrhythmias (except in patients with a functioning artificial pacemaker).
3. Known or suspected bronchoconstrictive or bronchoospastic lung disease (e.g., asthma).
4. Known hypersensitivity to adenosine.

**WARNINGS**

**Cardiac Arrhythmias, Hypotension**

18% of patients developing AV block with Adenoscan, including first-degree (32%), second-degree (29%), and third-degree (5%) heart block. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenoscan can cause bradycardia, AV block should be used with caution in patients with pre-existing AV block or bundle branch block and should be avoided in patients with high-grade right or left AV node dysfunction (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Since pause has been rarely observed with adenosine infusions.

Hypotension

Adenoscan is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflex mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, anesthetic, or pericardial effusion, stenotic carotid artery disease with cerebrovascular insufficiency, or uncorrected hypotension, due to the risk of hypotension contraindicated for use in patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

**Hypertension**

Adenoscan is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflex mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, anesthetic, or pericardial effusion, stenotic carotid artery disease with cerebrovascular insufficiency, or uncorrected hypotension, due to the risk of hypotension contraindicated for use in patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

**Bronchoconstriction**

Adenoscan (adenosine) has been shown to cause bronchoconstriction in asthmatic patients, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with bronchial asthma and has not been reported to moderate exacerbation of their symptoms or have occurred during adenosine infusions in patients with obstructive pulmonary diseases. Adenoscan should be used with caution in patients with obstructive lung disease associated with bronchoconstriction (e.g., asthma, bronchitis, chronic obstructive pulmonary disease, etc.) and should be avoided in patients with bronchoconstriction or bronchospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

**PRECAUTIONS**

**Drug Interactions**

Intravenous Adenoscan (adenosine) has been given with other cardiospecific drugs (such as beta adrenergic blocking agents, calcium glycosides, and other antiarrhythmic drugs) without apparent adverse interactions, but the effectiveness of these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan should be used with caution in patients receiving these agents. The vasodepressor effects of Adenoscan are inhibited by adrenergic agents, such as yohimbine (e.g., caffeine and theophylline). The safety and efficacy of Adenoscan in the presence of these agents have not been systematically evaluated. The effects of Adenoscan are potentiated by nucleoside transport inhibitors, such as dipyridamole. The safety and efficacy of Adenoscan in the presence of dipyridamole is not systematically evaluated. Whenever possible, magnesium or calcium, or other agents that increase the calcium ion concentration, should be given to patients with a history of or who have been treated for heart failure. When magnesium or calcium is used in patients with cardiac disease, the serum levels of calcium and magnesium should be monitored closely, and the infusion should be discontinued if either level becomes elevated.

**Carbohydrates, Metabolism, Impairment of Fertility**

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenoscan was negative for genotoxicity with Adenoscan (adenosine) and Salmonella Ames Test) and Mammalian Microsome Assays.

Adenoscan, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of cellular responses, including cell cycle arrest, and may cause increased mutagenic or cytotoxic effects. It is not known whether Adenoscan is mutagenic, and it is not known whether Adenoscan is teratogenic or carcinogenic in animals. Adenoscan has been shown to be teratogenic in animals. Adenoscan has been shown to be teratogenic in animals. Adenoscan has been shown to be teratogenic in animals.

**Pregnancy Category C**

Animal reproduction studies have not been conducted with Adenoscan, nor have studies been performed in pregnant women. Because it is not known whether Adenoscan can cause fetal harm when administered to pregnant women, Adenoscan should be used during pregnancy only if clearly needed.

**Pediatric Use**

The safety and effectiveness of Adenoscan in patients less than 18 years of age have not been established.

**ADVERSE REACTIONS**

The following reactions with an incidence of at least 1% were reported with intravenous Adenoscan among 1,421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10% of the side effects occurred not with the infusion of Adenoscan but several hours after its discontinuation. All of the side effects that began coincident with the infusion resolved by 24 hours after the infusion was complete. In many cases, it is not possible to determine whether these late adverse events were related to the infusion of Adenoscan. (See table below.)

- **Flushing**
  - 44%
  - 44% (Gastrointestinal discomfort)
  - 49% (Second-degree AV block)

- **Cheek/limb discomfort**
  - 42%
  - 42% (Lightheadedness/nausea)

- **Dyspnea or urge to breathe deeply**
  - 29%
  - 29% (Upper extremity discomfort)

- **Headache**
  - 13%
  - 13% (St segment depression)
  - 13% (Bradycardia)
  - 13% (T wave inversion)

- **Tach, rate or rhythm**
  - 15%
  - 15% (First-degree AV block)
  - 15% (Atrial fibrillation)

- **Adverse experiences of any severity reported in less than 1% of patients include:**
  - **Body:** dizziness; back pain; weakness;
  - **Cardiovascular System:** nonfatal myocardial infarction; life-threatening ventricular arrhythmias; third-degree AV block; bradycardia; palpitation; sinus arrest; sinus pause; vomiting; 10 cardiac arrests; 10 episodes of second-degree AV block; 10 episodes of third-degree AV block; 10 episodes of atrioventricular block; 10 episodes of atrial fibrillation; 10 episodes of atrial flutter; 10 episodes of complete heart block; 10 episodes of heart block; 10 episodes of hypotension; 10 episodes of sinus arrest; 10 episodes of sinus pause; 10 episodes of sinus tachycardia; 10 episodes of syncope.
  - **Central Nervous System:** dizziness; emotional instability; tremors.
  - **Genitourinary System:** vaginal hemorrhage; urgency.
  - **Respiratory System:** cough.
  - **Special Senses:** blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; stomatitis; tongue discomfort.

**OVERDOSAGE**

The half-life of Adenoscan is less than 10 seconds and side effects of Adenoscan when used may occur rapidly when the infusion is discontinued, although delayed or persistent effects have been observed. Methylxanthines, such as caffeine and theophylline, have been used to effectively terminate persistent side effects. In controlled U.S. clinical trials, theophylline (55-125 mg IV slow intravenous injection) was used to abort Adenoscan side effects in less than 2% of patients.

**DOSEAG AND ADMINISTRATION**

- **For Intravenous Infusion Only:** Adenoscan should be given as a continuous peripheral intravenous infusion. The infusion rate should be titrated to provide an initial dose of 0.4 mg/kg infused for six minutes (total dose of 0.84 mg/kg.)

**CAUTION:** Federal law prohibits dispensing without prescription.

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Circle Reader Service Number 59
CT showed evidence of chest involvement, but no definite distant metastases...

Chest CT scans showing evidence of right retroclavicular mass, right hilar and mediastinal lymphadenopathy associated with right middle and right lower lobe consolidation, as well as possible superimposed mass and bilateral pleural effusion.

Abdominal CT scan showing no definitive evidence of metastatic disease.
**Patient History**

A middle-aged female, with a history of heavy smoking, presented with increasing dyspnea, abdominal pain and changes in her mental status. Chest CT revealed extensive disease. A biopsy of a right retroclavicular mass was positive for small cell lung carcinoma. Abdominal CT showed no definite evidence of metastases.

**Clinical Course**

After receiving a course of chemotherapy of cytoxan, adriamycin and vincristine, the patient’s mental status improved and her shortness of breath and abdominal pain resolved. Follow-up OctreoScan studies showed marked overall improvement.

**OctreoScan Scintigraphy**

OctreoScan whole body imaging identified extensive activity in the head, chest, abdomen, pelvis, and spine. OctreoScan SPECT imaging localized chest lesions to the right retroclavicular, right hilar and mediastinal regions, as well as the thoracic spine, confirming the findings seen on chest CT.

**Decisive Clinical Information**

This case illustrates the benefits of OctreoScan imaging in the detection of small cell lung carcinoma, the whole body evaluation for distant metastases which may sometimes not be obvious on CT scanning, as well as for the follow-up of therapeutic response to treatment.
WARNINGS

2. Exposure to therapeutic levels of pentetreotide should not be followed by a totally fasting period of more than 6 hours. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labelled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacodyl or lactulose) be given to the patient starting the evening before the radiotracer is administered, and continuing for 48 hours after injection. Fasting is only necessary during this period as a support both to renal excretion and the bowel-cleansing process. In a patient with an insulinaemic hypoglycaemia be undertaken only after consultation with an endocrinologist.

The recommended intravenous dose for planar imaging is 111 MBq (3.0 mCi) of indium-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for SPECT imaging is 222 MBq (6.0 mCi) of indium-111 pentetreotide.

The dose should be confirmed by a suitably calibrated radioactivity ionization chamber immediately before administration.

As with all intravenously administered products, OctreoScan should be inspected visually for particulate matter and degradation prior to administration, whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with applicable regulations.

Aesthetic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves should be worn during the administration procedure.

Do not administer OctreoScan in TPN solutions or through the same intravenous line.

The estimated radiation doses to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Koning, et al.

<table>
<thead>
<tr>
<th>Planar OctreoScan</th>
<th>SPECT OctreoScan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knees</td>
<td>54.18</td>
</tr>
<tr>
<td>Liver</td>
<td>12.15</td>
</tr>
<tr>
<td>Spleen</td>
<td>73.66</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>147.73</td>
</tr>
<tr>
<td>Testes</td>
<td>6.34</td>
</tr>
<tr>
<td>Doses</td>
<td>4.89</td>
</tr>
<tr>
<td></td>
<td>9.79</td>
</tr>
<tr>
<td>Adrenals</td>
<td>2.90</td>
</tr>
<tr>
<td></td>
<td>5.80</td>
</tr>
<tr>
<td>Small intestine</td>
<td>3.46</td>
</tr>
<tr>
<td></td>
<td>6.91</td>
</tr>
<tr>
<td></td>
<td>30.42</td>
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<tr>
<td></td>
<td>60.48</td>
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<td>5.67</td>
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<td></td>
<td>11.34</td>
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<td>4.78</td>
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<td>5.75</td>
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<td>15.11</td>
</tr>
<tr>
<td></td>
<td>7.43</td>
</tr>
<tr>
<td></td>
<td>14.86</td>
</tr>
</tbody>
</table>

1. Values listed include a correction for a maximum of 0.1% indium-114m radiocontaminant at calibration.


3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.

4. Estimated according to ICRP Publication 53.

HOW SUPPLIED

The OctreoScan kit, NDC 0019-9050-40, is supplied with the following components:

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
   - 10 μg pentetreotide ([N-D-ethyl-N,N-dimethyl-L-histidine-N,N,N'-trifluoroacetic acid]-N'-acetyl-D-phenylalanine-L-hemicyclamide-L-phendylalanine-L-tyrosyl-L-lysyl-L-tryptophyl-L-lysyl-L-
   - threonine cyclic (2-[N,N-dimethylamino] propylamide), (also known as OctreoScan DTPA),
   - 2.0 mg penta acetic acid (2,5-dihydroxyphenylacetic acid),
   - 4.9 mg threonol citrate, anhydrous,
   - 0.37 mg choline, anhydrous, and
   - 10.0 mg histamine.

Before lyophilization, indium hydroxide or hydrochloric acid may have been added for pH adjustment. The vial contains sterile and non-pyrogenic. No bacteriostatic preservative is present.

2. A 10-mL vial of Indium-111 Chloride Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium-111 chloride in 0.02 mL H2O at time of calibration. The vial also contains leric chloride at a concentration of 3.5 μg/mL. The vial is sterile and non-pyrogenic. No bacteriostatic preservative is present.

In addition, the kit also contains the following items: (1) a 25 G x 5½" needle (B-D Monodoc) used to transfer Indium-111 Chloride Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

Circle Reader Service Number 110
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