Introducing

Nephroflow™

IODOHIPPURATE SODIUM I 123 INJECTION

Normal Transplant Renogram

NEPHROFLOW, Iodohippurate Sodium I 123 Injection, 1.0 mCi

High Count Rate
High Detector Efficiency

Iodohippurate Sodium I 131 Injection, 0.15 mCi

Low Count Rate
Low Detector Efficiency

NEPHROFLOW provides better counting statistics and higher data density.

To Order call (800) MEDI-123

1 Reference: Data on file, Medi-Physics, Inc., Richmond, CA
Particularly useful in obstructed patients
Slight advantage in photon intensity
Major advantage in ¼ inch crystal efficiency
Imaging should be performed as close to calibration time as possible

Comparison of I 123 and I 131

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>I 123</th>
<th>I 131</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of Decay</td>
<td>Electron capture</td>
<td>Beta-</td>
</tr>
<tr>
<td>Half-Life</td>
<td>13.2 hours</td>
<td>193 hours</td>
</tr>
<tr>
<td>Principal Gamma Energy (keV)</td>
<td>159</td>
<td>364</td>
</tr>
<tr>
<td>Intensity</td>
<td>84%</td>
<td>82%</td>
</tr>
<tr>
<td>Half-Value layer, lead, cm</td>
<td>0.037</td>
<td>0.24</td>
</tr>
<tr>
<td>Detection Efficiency</td>
<td>74.5%</td>
<td>22.5%</td>
</tr>
</tbody>
</table>

DESCRIPTION: Iodohippurate Sodium I 123 Injection is supplied as a sterile, aqueous, isotonic saline solution for intravenous administration. Each milliliter of the solution contains 37 megabequerels (1 millicurie) Iodohippurate Sodium I 123 at calibration time, 2 milligrams Iodohippurate Sodium, 1 percent benzyl alcohol (as a preservative), 0.9 milligrams per milliliter sodium chloride for isotonicity, and up to 0.1 percent ethanol. The solution is buffered with sodium phosphate and the pH is adjusted to 7.0-8.5 with sodium hydroxide or hydrochloric acid. The radionuclidian composition at calibration time is not less than 94.7 percent I 123, not more than 4.8 percent I 124, and not more than 0.5 percent all others (I 125, I 126, I 130, Na 24, Te 121). The radionuclidian composition at expiration time is not less than 95.5 percent I 123, not more than 12.9 percent I 124, and not more than 1.6 percent all others.

INDICATIONS AND USAGE: Iodohippurate Sodium I 123 Injection is a diagnostic aid in determining renal function, renal blood flow, and urinary tract obstruction, and as a renal imaging agent.

CONTRAINDICATIONS: None Known.

WARNINGS: None Known.

PRECAUTIONS:

General
The contents of the vial are radioactive. Adequate shielding of the preparation must be maintained at all times.
Do not use after the expiration time and date (24 hours after calibration time) stated on the label.
The prescribed Iodohippurate Sodium I 123 dose should be administered as soon as practical from the time of receipt of the product (i.e., as close to calibration time as possible) in order to minimize the fraction of radiation exposure due to relative increase of radionuclidian contaminants with time.
Iodohippurate Sodium I 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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long term animal studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or whether Iodohippurate Sodium I 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 Iodohippurate Sodium I 123 can cause fetal harm when administered to a pregnant woman, or can affect reproductive capacity. Iodohippurate Sodium I 123 should be given to a pregnant woman only if clearly needed.
Ideally, examinations using radiochemicals, especially those elective in nature, in women of childbearing capability should be performed during the first few days following the onset of menses.

Nursing Mothers
Since Iodine-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: As with all organic iodine containing compounds, the possibility of allergic reactions must be kept in mind. Nausea, vomiting, and fainting have been reported in conjunction with the administration of Iodohippurate Sodium I 123.

HOW SUPPLIED: Iodohippurate Sodium I 123 Injection is supplied in nominal 3.5 ml vials as a sterile, aqueous, isotonic saline solution for intravenous injection. Each milliliter contains 37 megabequerels (1 millicurie) of Iodohippurate Sodium I 123 at calibration time.

It is available, in individual vials, in the following sizes:
MPI Catalog No. 2041: 1 ml and 37 megabequerels (1 mCi) per vial
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A Fact Book

Edited by
A. Bertrand Brill, M.D.

This book represents a conscientious attempt to provide an unbiased, up-to-date source of knowledge regarding the potential long- and short-term effects of radiation exposure to humans. Because radiation exposure is an important and controversial topic, so much material is available. This fact book contains a concise reference list for readers wishing to obtain additional, or more detailed, information.

Important new sources of information provided the stimulus for publishing the 1985 updates to keep the fact book current. New reports issued by UNSCEAR, ICRP, and NCRP and references to recent publications of findings among Japanese A-bomb survivors have been added.

Available alone, or included with the original document, the 1985 updates will prove indispensable to a wide range of physicians, scientists, engineers, and technologists involved in the field.

“Only when information issued in a publication such as this becomes widespread and understood can rationality prevail in the public’s attitude toward low-level radiation.”

— from the Foreword by Rosalyn Yalow, Ph.D. Nobel Laureate

Contents

• Glossary, Units, and Conversion Factors
• Radiobiology
• Radiation Doses
• Late Somatic Effects of Low Doses of Ionizing Radiation
• Genetic Effects
• Risks—Statistical Facts and Public Perception
• Questions and Answers
• Appendix: Sources of Documents
• References
• Recommended Readings

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By Philip J. Robbins

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Please see adjacent page for brief summary.
DESCRIPTION
MacroTec is a sterile, nonpyrogenic, lyophilized preparation of albumin aggregated. Each 5 ml vial of MacroTec contains 1.5 mg of Albumin Aggregated, 10.0 mg Albumin Human, 0.07 mg (minimum) stannous chloride ([SnCl2·2H2O]) and 0.19 mg total tin, maximum (as stannous chloride, SnCl2·2H2O) 1.8 mg of sodium chloride with trace amounts of sodium acetate, acetic acid and hydrochloric acid. MacroTec contains no preservatives. The pH of the reconstituted product is between 3.8 and 8.0.

The aggregated particles are formed by denaturation of Albumin Human in a heating and precipitation process. Each vial contains 1-8 million particles, 90% of which are between 10 and 90 microns in size. The average size is 20 to 40 microns; no particles are greater than 150 microns.

Reconstitution of MacroTec with sterile sodium pertechnetate Tc99m forms an aqueous suspension of Technetium Tc99m Albumin Aggregated for diagnostic use by Intravenous injection. No less than 90% of the pertechnetate Tc99m added to the reaction vial is bound to the aggregates of preparation time and remains bound throughout the 6-hour lifetime of the suspension.

INDICATIONS AND USAGE
Lung Imaging
MacroTec (Technetium Tc 99m Albumin Aggregated Injection) is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of the pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Isotopic Venography
MacroTec is also indicated for use in isotopic venography as an adjunct in the screening, diagnosis and management of deep vein thrombosis in the lower extremities.

Combined isotopic venography of the lower extremities and the pulmonary vasculature may be performed.

CONTRAINDICATIONS
Technetium Tc 99m Albumin Aggregated Injection should not be administered to patients with severe pulmonary hypertension.

The use of Technetium Tc 99m Albumin Aggregated Injection is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

WARNINGS
The literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

PRECAUTIONS
General
In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

The intravenous administration of any particulate material such as Albumin Aggregated imposes a temporary, small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of Albumin Aggregated is possibly hazardous in acute car pulmonary and other states of severely impaired pulmonary blood flow.

The components of the MacroTec (Technetium Tc 99m Albumin Aggregated Kit) are sterile and non-pyrogenic. It is essential to follow directions carefully and adhere to strict aseptic procedures during preparation.

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient.

The contents of the kit before preparation are not radioactive. However, after the sodium pertechnetate Tc99m is added, adequate shielding of the final preparation must be maintained.

The technetium Tc-99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after formulation.

Technetium Tc 99m Albumin Aggregated Injection is a physically unstable suspension and consequently the particles settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles.

If blood is drawn into the syringe, unnecessary delay prior to injection may result in clot formation.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the 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.

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to clinical personnel.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc-99m Albumin Aggregated Injection affects fertility in males or females.

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc 99m Albumin Aggregated Injection. It is also not known whether Technetium Tc 99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m Albumin Aggregated Injection should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers
Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use
The lowest possible number of particles should be used in the right-to-left shunting, in neonates and in severe pulmonary disease.

ADVERSE REACTIONS
Although adverse reactions specifically attributable to the Technetium Tc 99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

HOW SUPPLIED
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High bone to soft tissue ratios: Usually 40% to 50% uptake within 3 hours. Up to 50% is usually cleared by urinary excretion within the first 3–6 hours.

Stabilized with ascorbic acid, providing in-vitro stability for the 6 hours until expiration, by utilizing an MPI process so unique that we had it patented.*

DESCRIPTION: Each kit contains 10 multidose reaction vials, each containing 10 mg of medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.29 mg), and 2 mg ascorbic acid. The contents of the vial are sterile, pyrogen-free, lyophilized and sealed under nitrogen. The pH has been adjusted to 4-8 with hydrochloric acid and sodium hydroxide.

Administration is by intravenous injection for diagnostic use, after reconstitution with oxidant-free Sodium Pertechnetate Tc 99m Injection. The product as supplied is sterile and pyrogen-free.

The precise structure of stannous Technetium Tc 99m medronate complex is unknown at this time.

INDICATIONS AND USAGE: Technetium Tc 99m Medronate Injection may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNINGS: This class of compound is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to, hypocalcemia (i.e., alkalosis).

Preliminary reports indicate impairment of brain scans using Sodium Pertechnetate Tc 99m injection which have been preceded by a bone scan using an agent containing stannous ions. This impairment may result in false-positive or false-negative brain scans. It is recommended, where feasible, that brain scans precede bone imaging procedures. Alternatively, a brain imaging agent such as Technetium Tc 99m Pertechnetate Injection may be employed.

PRECAUTIONS:

General

The contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc 99m Injection is added, adequate shielding of the final preparation must be maintained.

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Medronate Injection and are NOT to be administered directly to the patient.

Technetium Tc 99m Medronate Injection, as well as other radioactive drugs, must be handled with care. Once Sodium Pertechnetate Tc 99m Injection is added to the vial, appropriate safety measures should be used to minimize external radiation to clinical occupational personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

To minimize radiation dose to the bladder, the patient should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next 4–6 hours.

Technetium Tc 99m Medronate Injection should be formulated within six (6) hours prior to clinical use. Optimal imaging results are obtained one to four hours after administration. The solution should not be used if cloudy.

The vials should not be used after the expiration date shown on the label. Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the 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 Technetium Tc 99m Medronate Injection affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Medronate Injection. It is also not known whether Technetium Tc 99m Medronate Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Medronate Injection should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those effective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Although adverse reactions have not been reported that are specifically attributable to the use of Technetium Tc 99m Medronate Injection, allergic dermatological manifestations (erythema and other allergic reactions) have been reported with similar agents.

HOW SUPPLIED:

Kit Contents

10 STERILE REACTION VIALS (10 cc silver aluminum overcoat), each containing,((a) in lyophilized form and under nitrogen atmosphere, 10 mg of medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.29 mg), and 2 mg ascorbic acid. Hydrochloric acid and sodium hydroxide have been added for pH adjustment prior to lyophilization.

20 PRESSURE-SENSITIVE LABELS for final preparation of Technetium Tc 99m Medronate Injection.

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