Kit for the Preparation of Technetium Tc99m Mebrofenin
For Intravenous Use, For Diagnostic Use
Rx Only

- 45 mg mebrofenin per vial
- Indicated for hepatobiliary imaging
- Room temperature storage both before and after reconstitution
- Choice of 5-vial kit or 30-vial convenience pack
Technetium Tc 99m decay by isomeric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is listed in Table 1.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Principal Radiation Emission Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation</td>
<td>Gamma-2</td>
</tr>
<tr>
<td>Mean % per Disintegration</td>
<td>89.07</td>
</tr>
<tr>
<td>Mean Energy (keV)</td>
<td>140.9</td>
</tr>
</tbody>
</table>

When sterile, pyrogen-free sodium pertechnetate Tc 99m is added to the vial, the diagnostic agent Technetium Tc 99m Mebrofenin is formed for administration by intravenous injection.

**PHYSICAL CHARACTERISTICS**

Technetium Tc 99m decays by isomeric transition with a sodium pertechnetate Tc 99m supply may, thus, be evaluated in the light of the total clinical picture in the safe use and handling of radionuclides.

**INDICATIONS AND USAGE**

Technetium Tc 99m Mebrofenin is indicated as a hepatobiliary imaging agent.

**CONTRAINDICATIONS**

Hyperosponsivity to this compound.

**WARNINGS**

The theoretical possibility of allergic reactions should be considered in patients who receive multiple doses.

**PRECAUTIONS**

General

Contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Mebrofenin and are not to be administered directly to the patient.

Delayed or non-visualization of the gallbladder may occur in the immediate post-prandial period or after prolonged fasting or parenteral feeding. Functional biliary obstruction may accompany chronic cholecystitis or pancreatitis. In addition, patients with hepatic cellular disease may show non-visualization or delayed visualization of the gallbladder. Delayed intestinal transit may also be noted in such patients. Juvenile hepatitis may be associated with gallbladder nonvisualisation and the failure to visualize activity in the intestine. Administration of meperidine or morphine may delay intestinal transit of the imaging agent and result in nonvisualisation. Septic patients may show absence or delayed hepatobiliary clearance. Thus, a positive finding does not of itself permit a differential diagnosis of any of the above conditions and should be evaluated in the light of the total clinical picture and results of other diagnostic modalities.

The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration.

The Technetium Tc 99m labeling reactions involved in preparing the agent depend on maintaining the technetium ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc 99m supply may, thus, adversely affect the quality of the radiopharmaceutical. Hence, sodium pertechnetate Tc 99m containing oxidants should not be employed.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

To 99m Tc Mebrofenin should be formulated no more than 6 hours prior to clinical use.

**CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY**

No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Mebrofenin may affect fertility in males or females.

**PREPREGNANCY, PREGNANCY CATEGORY C**

Animal reproduction studies have not been conducted with Technetium Tc 99m Mebrofenin. It is not known whether Technetium Tc 99m Mebrofenin causes fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Mebrofenin should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential risks.

**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 below the age of 18 have not been established.

**ADVERSE REACTIONS**

Urticaria and rash have been rarely reported with the use of Technetium Tc 99m Mebrofenin since market introduction. Rare cases of chills and nausea have been reported with related compounds. Infrequently, death has been reported in association with the use of this class of agents.

**DOSEAGE AND ADMINISTRATION**

The maximum recommended dose range of Technetium Tc 99m Mebrofenin in the average patient (70 kg) is:

- Nonjaundiced patient: 74 - 188 MBq (2-5 mCi)
- Jaundiced patient with serum bilirubin level greater than 1.5 mg/dL: 111-370 MBq (3-10 mCi)

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

The patient should be in a fasting state, 4 hours is preferable. False positives (non-visualisation) may result if the gallbladder has been emptied by ingestion of food.

An interval of at least 24 hours should be allowed before subsequent examinations.

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

**RADIATION DOSIMETRY**

The estimated absorbed radiation doses to organs and tissues of an average subject (70 kg) from an intravenous injection of 370 MBq (10 millicuries) of Technetium Tc 99m Mebrofenin are shown in Table 4.

<table>
<thead>
<tr>
<th>TABLE 4</th>
<th>Estimated Absorbed Radiation Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue</td>
<td>Normal Subject</td>
</tr>
<tr>
<td></td>
<td>mg/sr/MBq</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.2</td>
</tr>
<tr>
<td>Liver</td>
<td>4.7</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>13.1</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.3</td>
</tr>
<tr>
<td>Intestine</td>
<td>2.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>2.0</td>
</tr>
<tr>
<td>Upper Large Intestinal Wall</td>
<td>0.3</td>
</tr>
<tr>
<td>Lower Large Intestinal Wall</td>
<td>3.9</td>
</tr>
</tbody>
</table>

The method of calculation:


(2) Values for B. S. "Dosages Derived per Unit Cumulated Activity" for Radiotracers and Organisms, IRR Publ No. 11 (1975).

Radiopharmaceutical products are manufactured in compliance with the U.S. Pharmacopeia, National Formulary, and Massachusetts Regulation 105, or under equivalent license of the U.S. Nuclear Regulatory Commission or an Agreement State.

**HUMAN FACTORS**

Hazard categories appropriate for radiopharmaceutical products are designated for use by the licensee pursuant to the conditions specified in 318-332.

**STORAGE**

Store the kit as supplied at 20-25°C (68-77°F) [See USP] prior to and following reconstitution. Use within 6 hours of reconstitution.

**Rx only**

NDC-045567-0455-1 (5 Vial Kit)
NDC-045567-0455-2 (30 Vial Kit)

**50 Dighton Road Bedford, MA 01730**
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Manufactured By

**pharmaceutical**

For Intraocular Use