CHOLETEC® (Kit for the Preparation of Technetium Tc 99m Mebrofenin)

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Hypersensitivity to this compound.

WARNINGS AND PRECAUTIONS
Allergic reactions should be considered in patients who receive multiple doses.

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 hepatocellular disease may show non-visualization or delayed visualization of the gallbladder. Delayed intestinal transit may also be noted. Juvenile hepatitis may be associated with gallbladder non-visualization and the failure to visualize activity in the intestine. Administration of meperidine or morphine may delay intestinal transit of the imaging agent and may result in non-visualization. Septic patients may show absent or delayed hepatobiliary clearance. Thus, a positive finding does not in 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.

Aseptic procedures 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 stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc 99m supply may adversely affect the quality of the radiopharmaceutical therefore, sodium pertechnetate Tc 99m containing oxidants should not be used.

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

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.

Tc 99m Mebrofenin should be formulated no more than 18 hours prior to clinical use.

Pregnancy: It is not known whether Technetium Tc 99m Mebrofenin can cause 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 hazards.

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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for Choletec (Kit for the preparation of Technetium Tc 99m Mebrofenin).

Choletec is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540, by Jubilant HollisterStier LLC, Spokane, WA 99207.

Choletec is a registered trademark of Bracco Diagnostics Inc.

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