Hepatolite®
Kit for the Preparation of Technetium Tc99m Disofenin for Injection
For Diagnostic Use

- Specifically indicated to diagnose and rule out acute cholecystitis
- Fast preparation is ideal for stat procedures
- Effective imaging even in patients with elevated bilirubin levels
- Proven hepatobiliary kinetics
- Room-temperature storage both before and after reconstitution
- Choice of 5-vial kit or 30-vial Convenience Pack

www.pharmalucence.com
TECHNETIUM Tc99m DISOFENIN

Object: kit for the preparation of Technetium Tc99m Disofenin for injection

CLINICAL PHARMACOLOGY

Disofenin (Hepatolite) is an inorganic acid derivative with no known pharmacologic actions at the dosages recommended.

The technetium Tc99m labeling reactions involved in preparing the agent depend on maintaining the technetium ions in the radiopharmaceutical formulation. Any oxidant present in the sodium pertechnetate Tc99m solution may thus cause the technetium ions to be reduced. Hence, sodium pertechnetate Tc99m solution 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility studies have not been conducted with Technetium Tc99m Disofenin.

Pregnancy Category C

Animal reproductive and teratology studies have not been conducted with Technetium Tc99m Disofenin to evaluate carcinogenic potential or whether Technetium Tc99m Disofenin affects fertility in males or females.

Nursing Mothers

Technetium Tc99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

Geriatric Use

Clinical studies of Hepatolite did not include sufficient numbers of aged subjects and are not representative of the very young from 16 to 17 years of age. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, other drugs used in conjunction with hepatic scintigraphy may be of concern in the elderly patient. A cautious approach is recommended.

CONTRAINDICATIONS

None known.

WARNINGS

The possibility of allergic reactions should be considered.

PRECAUTIONS

The preparation contains no bacteriostatic preservative. Technetium Tc99m Disofenin should also be used within six hours of preparation.

In cases where there has been no visualization of the gallbladder following 60 minutes of scanning, the technetium Tc99m Disofenin may be carefully administered to patients who have a contraindication to the use of narcotics. There should be clear evidence of an acute common duct, such as evidence of a cholangiographic study, or a low bile salt index. Failure to visualize the gallbladder during the 30-minute observation prior to injection should be considered a contraindication for technique Tc99m Disofenin for injection.

The preparation should be used with caution in patients with a history of allergy to contrast media. A careful history of allergies should be obtained before use of the Technetium Tc99m Disofenin for Injection. In patients with a history of allergic reactions to contrast media, it may be preferable to use an alternative radiopharmaceutical.

In patients with a history of anaphylaxis to shellfish, other fish, or crustaceans, the use of Technetium Tc99m Disofenin for Injection should be considered in consultation with a physician experienced in the management of anaphylactic reactions.

The technetium Tc99m labeling reactions involved in preparing the agent depend on maintaining the technetium ions in the radiopharmaceutical formulation. Any oxidant present in the sodium pertechnetate Tc99m solution may thus cause the technetium ions to be reduced. Hence, sodium pertechnetate Tc99m solution 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility studies have not been conducted with Technetium Tc99m Disofenin. It is also not known whether Technetium Tc99m Disofenin can cause fetal harm when administered to a pregnant woman or can affect reproductive capability. There have been no studies in pregnant women. Technetium Tc99m should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Technetium Tc99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

Geriatric Use

Clinical studies of Hepatolite did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, other drugs used in conjunction with hepatic scintigraphy may be of concern in the elderly patient. A cautious approach is recommended.

CONTRAINDICATIONS

None known.

WARNINGS

The possibility of allergic reactions should be considered.

PRECAUTIONS

The preparation contains no bacteriostatic preservative. Technetium Tc99m Disofenin should also be used within six hours of preparation.

In cases where there has been no visualization of the gallbladder following 60 minutes of scanning, the technetium Tc99m Disofenin may be carefully administered to patients who have a contraindication to the use of narcotics. There should be clear evidence of an acute common duct, such as evidence of a cholangiographic study, or a low bile salt index. Failure to visualize the gallbladder during the 30-minute observation prior to injection should be considered a contraindication for technique Tc99m Disofenin for injection.

The preparation should be used with caution in patients with a history of allergy to contrast media. A careful history of allergies should be obtained before use of the Technetium Tc99m Disofenin for Injection. In patients with a history of anaphylaxis to shellfish, other fish, or crustaceans, the use of Technetium Tc99m Disofenin for Injection should be considered in consultation with a physician experienced in the management of anaphylactic reactions.

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