



GE Healthcare
Life Sciences

100 Results Way
Marlborough, MA 01752

June 22, 2015

Dear Valued GE Healthcare Customer,

Supply Update for GE Healthcare-manufactured DMSA

GE Healthcare regrets to inform you that the expected return of DMSA, indicated as an aid for the scintigraphic evaluation of renal parenchymal disorders, to the global market has been delayed until approximately August 2016. Until that time we will be unable to supply DMSA (Kit for the Preparation of Technetium Tc99m Succimer Injection) to our customers.

This supply interruption is due to delays in changing a supplier for one of the product's key components and the complexities related to the relocation of manufacturing of the final product. Both activities require extensive final product quality-control validation tests.

We will continue to work diligently to resolve the situation and will update you on progress regarding product will, again, be available..

We sincerely regret this inconvenience to you and your patients, but we trust that this information will be helpful to you and your colleagues in managing your facilities and nuclear medicine departments.

If you would like any further clarification, please do not hesitate to contact your local GE Healthcare Sales Specialist or GE Healthcare Medical Affairs, 800 654 0118 (Option 2, then Option 3)

Yours sincerely,

A handwritten signature in black ink that reads "James A. Kaufman".

James A. Kaufman
Global Product Leader - SPECT
Life Sciences - Core Imaging
GE Healthcare

Important Risk and Safety Information About DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection

INDICATIONS: Technetium Tc99m succimer is to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders. **CONTRAINDICATIONS:** None known. **WARNINGS AND PRECAUTIONS:** The contents of the DMSA vial are intended only for use in preparation of technetium Tc99m succimer injection and are not to be administered directly to the patient. DMSA should be used between 10 minutes and four hours following reconstitution. Any unused portion should be discarded after that time. Some patients with advanced renal failure may exhibit poor renal intake of Tc99m DMSA. It has been reported that satisfactory images may be obtained in some of these patients by delaying imaging for up to 24 hours. **Renal Clearance:** This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. **Pregnancy:** It is unknown whether Tc99m succimer can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. Tc99m succimer should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus. **Nursing Mothers:** Technetium Tc99m is excreted in human milk during lactation. It is unknown whether succimer is excreted in human milk. Formula feedings should be substituted for breastfeedings for 60 hours after administration. **Pediatrics:** Safety and effectiveness in pediatric patients have not been established. **Geriatrics:** Reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. **Adverse Reactions:** Rare instances of syncope, fever, nausea, and maculopapular skin rash have been reported.

Prior to DMSA administration, please read the Full Prescribing Information.