

URGENT Drug Recall

DTPA

Kit for the Preparation of Technetium Tc99m Pentetate Injection

Lots 2414, 2416

August 2, 2010

Dear Customers and Distributors:

Recent testing data of Pharmalucence DTPA (Kit for the Preparation of Technetium Tc99m Pentetate Injection), lots 2414 and 2416, indicate that these two lots do not maintain 90% Radiochemical Purity (RCP) for up to six hours after reconstitution with up to 160 mCi of Technetium Tc99m. The DTPA package insert instructions state that the reconstituted product may be used up to 6 hours after reconstitution. Therefore, Pharmalucence is initiating a recall of our DTPA product. Additionally, until further notice, we will no longer market or distribute Pharmalucence DTPA.

Having greater than 10% unbound Tc-99m radioactivity will cause uptake in several organs (thyroid, stomach, salivary gland) and slower clearance of radioactivity from the blood as compared to the bound, Tc-99m-DTPA. This altered biodistribution will be noticeable on the scintigrams and precludes most if not all diagnostic readings. The scans will be clinically nondiagnostic and a repeat study would be required.

Pharmalucence Part #	Date of Manufacture	NDC #:	Expiration	Lot #'s:	Action
ANDTP05 ANDTP30	March 2009	45567-0010-1 45567-0010-2	Sept 2010	2414	Immediately return to Pharmalucence credit.
ANDTP05 ANDTP30	Dec 2009	45567-0010-1 45567-0010-2	June 2011	2416	Immediately return to Pharmalucence credit.

See reverse side for Recall Processing Instructions

DTPA Lots 2414 and 2416 Recall Instructions

- Please examine your inventory for the affected lots; **DTPA Lot 2414 and Lot 2416**.
- If any vials of these lots remain in your inventory, please cease use of these lots and proceed with instructions below outlining how to return these vials for sales credit.
- If you are a Radiopharmacy or other Distributor of this product, please contact your Customers to ensure all affected Customers are notified of this recall.
- For immediate needs, including orders and medical / clinical inquiries contact:

Pharmalucence Customer Service Phone
800-221-7554

- Upon receipt of this notice, please fill out the attached Product Return Form with information concerning your inventory of DTPA (Kit for the Preparation of Technetium Tc99m Pentetate Injection), Lots 2414 and 2416 and your contact information. This form should be completed even if you no longer have any remaining inventory. Fax the completed form to Pharmalucence. Retain the original for inclusion in your return shipment.

Pharmalucence Customer Service Fax Number: **781-275-2634**

Ship any product to be returned via Federal Express, Standard Overnight, Charge to Pharmalucence FEDEX Account # 1194-0161-5:

Pharmalucence, Inc., 54 Loomis Street, Bedford, MA 01730

- Pharmalucence will provide sales credit for returned material within 5 business days to address the recalled product lot.

Pharmalucence is conducting this recall with the knowledge of the Food and Drug Administration. We appreciate your cooperation with this recall program and regret any inconvenience that it may cause. Any updates to this notice will be posted on the Pharmalucence website at www.pharmalucence.com.

Thank you for your continued support of Pharmalucence.

Sincerely,



John J. Felock
Director of Marketing and Sales
Pharmalucence, Inc.

**URGENT DRUG RECALL
PRODUCT RETURN FORM**

DTPA
Kit for the Preparation of Technetium Tc99m Pentetate Injection
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**Ship returns via Federal Express, Standard Overnight, Bill Recipient to:
Pharmalucence, Inc., 54 Loomis Street, Bedford MA 01730**

Product Return Authorization #: PRA-2010-017

Customer Name: _____

Customer Address: _____

Telephone Number: _____

Email Address: _____

Lot Number	5 vial kits returned	30 vial packs returned	Partial Kits Returned (# of vials)
2414			
2416			

Check this box if you have no inventory from the lots referenced above to return.

I hereby certify return to Pharmalucence Inc., all inventory in the possession of this organization from lots referenced in this recall action, if applicable.

Customer Signature _____

Date: _____

Fax this form to Pharmalucence Customer Service at (781) 275-2634