

URGENT: DRUG RECALL



December 10, 2001
Event ID:

PRODUCT	<p>Product: VAQTA® (Hepatitis A Vaccine, Inactivated)</p> <p>NDC: 0006-4844-00 / 0006-4844-38 Strength: 50U/1 mL of Hepatitis A virus protein Package Size: 1 mL single-dose or package of 5 prefilled syringe(s) Lot Number: 0030L (10/29/03), 0460L (10/30/03), 0031L (11/05/03), (Expiration Date): 0031LSA1 (11/05/03), 0507L (02/17/04), 0525L (2/18/04), 0524L (2/18/04), 0523L (2/15/04)</p> <p>NDC: 0006-4845-00 / 0006-4845-38 Strength: 25U/0.5 mL of Hepatitis A virus protein Package Size: 0.5 mL single-dose or package of 5 prefilled syringe(s) Lot Number: 1761H (11/02/01), 1937H (11/16/01), 0159J (12/8/01), (Expiration Date): 0158J (1/11/02), 0115K (2/17/02), 0580J (2/19/02), 0746J (3/4/02), 1407J (3/10/02), 0745J (3/10/02) 0952J (4/13/02), 1915J (4/13/02), 1751J (5/16/02), 0117K (5/17/02), 1750J (5/18/02), 1871J (10/18/02), 1802JSA2 (10/24/02), 1802J (10/24/02), 0118K (12/22/02), 0309K (12/22/02), 0330K (12/22/02), 0547K (12/23/02), 0680K (2/9/03), 0548K (2/10/03), 0692K (3/29/03), 0852K (4/2/03), 1200K (5/31/03), 0714L (6/2/03), 1178K (6/3/03), 0430L (8/25/03), 1628K (8/25/03), 0715L (9/20/03), 0716L (9/20/03)</p> <p>Manufactured By: Merck & Co., Inc. West Point, USA</p>
REASON	Recent investigation indicates that some syringes within the above mentioned lots may have antigen levels below the product specification limit. Persons vaccinated with VAQTA® in prefilled syringes from the indicated lots may be insufficiently protected against hepatitis A.
ACTION	<ol style="list-style-type: none">1. Stop distributing, and quarantine the indicated lots of product.2. Please carry out a physical count and record this data on the Business Reply Card and the Packing Slip, which are included with this letter.3. Mail the postage paid Business Reply Card even if you do not have the recalled product.4. Return the recalled product and Packing Slip using the prepaid Shipping Labels to: ATTN: NNC Dept. Merck Order Fulfillment Center 1645 Satellite Blvd. Duluth, GA 30097
RECALL INSTRUCTIONS	This recall is being conducted to the user level. If product has been further distributed you must contact all of your accounts to the Physician/Health Care Professional level. If your customers are not physicians/health care professionals, please instruct your customers that they need to notify their customers to the physician/health care professional level also. The attached Dear Doctor Letter

should be provided to physician/health care providers for further guidance with regard to patient care. No other lots, packages, or formulations are being recalled.

For medical questions, contact Merck's National Service Center at 800-672-6372. For shipping assistance please contact Merck's Order Management Center at 800-637-2579. For questions about the recall process, contact NNC at 800-668-4391.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

PRODUCT FOR RETURN - Vaccines

RETURNED PRODUCT IS TO BE SENT DIRECTLY TO:

ATTN: NNC Dept.
Merck Order Fulfillment Center
1645 Satellite Blvd.
Duluth, GA 30097

To ensure the issuance of proper credit and for the protection of our customers, acceptance of returned product will be subject to the following conditions:

- The enclosed packing list must accompany the returned product.
- The shipping carton must bear the name and address of the sender.

Merck & Co., Inc. will compensate customers affected by a product recall as follows:

- Credit for product will be issued at the direct price in effect at the time of purchase.
- Customers will be reimbursed for reasonable and customary administrative and handling costs as determined by Merck.
- Merck & Co., Inc. will pay actual transportation charges for product returned as a result of a recall.

BUSINESS REPLY CARD

Merck & Co., Inc.

VAQTA® (Hepatitis A Vaccine, Inactivated)

NDC 0006-4844-00 50U/1 mL of hepatitis A virus protein

LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND
0460L	30-Oct-03		0031L	5-Nov-03		0031LSA1	5-Nov-03		0525L	18-Feb-04	

NDC 0006-4844-38 50U/1 mL of hepatitis A virus protein

0030L	29-Oct-03		0523L	15-Feb-04		0507L	17-Feb-04		0524L	18-Feb-04	
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NDC 0006-4845-00 25U/0.5 mL of hepatitis A virus protein

0115K	17-Feb-02		0952J	13-Apr-02		0430L	25-Aug-03		1628K	25-Aug-03	
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NDC 0006-4845-38 25U/0.5 mL of hepatitis A virus protein

1761H	2-Nov-01		1937H	16-Nov-01		0159J	8-Dec-01		0158J	11-Jan-02	
0580J	19-Feb-02		0746J	4-Mar-02		0745J	10-Mar-02		1407J	10-Mar-02	
1915J	13-Apr-02		1751J	16-May-02		0117K	17-May-02		1750J	18-May-02	
1871J	18-Oct-02		1802J	24-Oct-02		1802JSA2	24-Oct-02		0118K	22-Dec-02	
0309K	22-Dec-02		0330K	22-Dec-02		0547K	23-Dec-02		0680K	9-Feb-03	
0548K	10-Feb-03		0692K	29-Mar-03		0852K	2-Apr-03		1200K	31-May-03	
0714L	2-Jun-03		1178K	3-Jun-03		0715L	20-Sep-03		0716L	20-Sep-03	

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, even if you do not have the recalled product. Thank you.

I have read the Recall Instructions, quarantined product as defined, and have notified our accounts on _____ (include date) via _____ (include method of notification).

Signature: _____ Title: _____

Printed Name: _____ Phone: _____

PACKING SLIP

Merck & Co., Inc.

VAQTA® (Hepatitis A Vaccine, Inactivated)

NDC 0006-4844-00 50U/1 mL of hepatitis A virus protein

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1915J	13-Apr-02		1751J	16-May-02		0117K	17-May-02		1750J	18-May-02	
1871J	18-Oct-02		1802J	24-Oct-02		1802JSA2	24-Oct-02		0118K	22-Dec-02	
0309K	22-Dec-02		0330K	22-Dec-02		0547K	23-Dec-02		0680K	9-Feb-03	
0548K	10-Feb-03		0692K	29-Mar-03		0852K	2-Apr-03		1200K	31-May-03	
0714L	2-Jun-03		1178K	3-Jun-03		0715L	20-Sep-03		0716L	20-Sep-03	

The following information is required to assure proper crediting: Debit

Memo: _____

Direct Purchase: Account # Name and address

THIS PRODUCT IS NOT FOR RESALE

Indirect Purchase: Name and address of distributor

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