

Important Information on VAQTA^â (Hepatitis A Vaccine, Inactivated) in prefilled syringes

Dear Doctor/Health Care Provider,

Re-tests of VAQTA[®] [Hepatitis A Vaccine, Inactivated] in prefilled syringes have revealed a decreased antigen content in some syringes below the established minimum specification. As a result, a possibility exists that **persons vaccinated with VAQTA^â in prefilled syringes from the indicated lots may be insufficiently protected against hepatitis A.**

Merck & Co., Inc. is voluntarily recalling the indicated lots [See Attachment I for all indicated lots] of VAQTA[®] in prefilled syringes. Patients who may have received doses from the indicated lots would have been vaccinated after May 29, 2001 with the adult formulation, (50U/1 mL), and after August 9, 1999 with the pediatric/adolescent formulation, (25U/0.5 mL).

The indicated lots should no longer be used. You are kindly requested to return any stock of the recalled VAQTA[®] in prefilled syringes to Merck according to the enclosed instructions or, if not purchased directly from Merck, to your distributor. Cold chain transport is not necessary.

The following are not affected by this recall:

- All VAQTA^â packaged in vials, and
- Lots of VAQTA^â packaged in syringes not on the attached list.

If you have questions with respect to returns please contact the Merck Order Management Center at **1 – 800 – 637 – 2579.**

For Individuals Vaccinated with Prefilled Syringes from Indicated Lots:

It is suggested that you review the records of patients who may have been vaccinated after the following dates with VAQTA[®] in prefilled syringes, to see if the indicated lots were used in such vaccination:

- Adult formulation (50U/1 mL): May 29, 2001
- Pediatric/adolescent formulation (25U/0.5 mL): August 9, 1999.

If in your clinical assessment, revaccination against hepatitis A and/or antibody testing is indicated for these patients, you may consider the following guideline:

Total number of doses of hepatitis A vaccine patient received	Antibody testing recommended	Result	Number of further doses for revaccination
2 (One or both doses from an indicated lot)	Yes 4 weeks after vaccination	Positive	0
		Negative	2*
1 (Dose from an indicated lot)	No	Not applicable	2*

* For time interval, please see the enclosed full Prescribing Information for VAQTA®. For some vaccinees it may be preferable to test antibody status after a single revaccination dose. Antibody testing may be done at the earliest 4 weeks after the first dose of revaccination. Vaccinees will be eligible for receipt of the second dose depending on the results of the antibody test

In order to determine the immunogenicity of the indicated lots of vaccine administered to your patient, Merck & Co., Inc. is negotiating a contract with a testing laboratory to determine the hepatitis A antibody concentration in these patients. If you choose to do antibody testing, the service by this laboratory will be free. Please contact Merck & Co., Inc. via telephone for a complete set of instructions.

Telephone no.: 1-800-439-4958

If revaccination doses are necessary, contact Merck & Co., Inc. via fax regarding re-supply of vaccine free of charge. Please send your written request to the following fax number, indicating the number of revaccination doses used and identifying your source of supply.

Fax-no.: 215-652-6700

For medical questions please call the Merck National Service Center at **1- 800 – 672 - 6372**.

Before prescribing, please read the enclosed Prescribing Information for VAQTA® [Hepatitis A Vaccine, Inactivated].

We do hope that you will understand these necessary measures.

Kind regards,

Thomas M. Vernon, M. D.
VP Policy, Public Health & Medical Affairs

The following table summarizes phone and fax numbers:

Questions with respect to returns	Telephone: 1 – 800 – 637 – 2579
Request of instructions for antibody testing	Telephone: 1 – 800 – 439 - 4958
Request of hepatitis A vaccine	FAX: 215 – 652 - 6700
Medical questions	Telephone: 1- 800 - 672- 6372

Attachment 1

NDC #	STRENGTH	PRODUCT DESCRIPTION	LOT #	EXP. DATE
0006-4844-00	50U/1 mL of hepatitis A virus protein	VAQTA®	0460L	30-Oct-03
			0031L	5-Nov-03
			0031LSA1	5-Nov-03
			0525L	18-Feb-04
0006-4844-38	50U/1 mL of hepatitis A virus protein	VAQTA®	0030L	29-Oct-03
			0523L	15-Feb-04
			0507L	17-Feb-04
			0524L	18-Feb-04
0006-4845-00	25U/0.5 mL of hepatitis A virus protein	VAQTA®	0115K	17-Feb-02
			0952J	13-Apr-02
			0430L	25-Aug-03
			1628K	25-Aug-03
0006-4845-38	25U/0.5 mL of hepatitis A virus protein	VAQTA®	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