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**INFORMATION RE: HAVRIX®
(HEPATITIS A VACCINE)**

**TIP CAPS OF THE PREFILLED SYRINGES MAY CONTAIN
NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS
IN LATEX SENSITIVE INDIVIDUALS**

July 29, 2010

Dear Healthcare Professional:

GlaxoSmithKline (GSK) Biologicals would like to inform you that the **tip caps of prefilled syringes in which HAVRIX is supplied may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.** Please note that cartons and Prescribing Information packaged in cartons of HAVRIX accompanied by this letter do not contain this information and are outdated. Revisions to the Prescribing Information are described below.

Updated Prescribing Information

The **outdated** Prescribing Information states that the tip caps of the prefilled syringes do not contain latex.

To reflect that the tip caps of the prefilled syringes may contain natural rubber latex, the following lists the **updated** content of the Prescribing Information:

- *Highlights of Prescribing Information – Recent Major Changes* states: “Warnings and Precautions, Hypersensitivity 07/2010”
- *Highlights of Prescribing Information – Warnings and Precautions* states: “One type of prefilled syringe has a tip cap which may contain natural rubber latex. The other type has a tip cap and a rubber plunger which contain dry natural latex rubber. Use of these syringes may cause allergic reactions in latex sensitive individuals.”
- *Warnings and Precautions – Hypersensitivity* Section 5.1 states: “HAVRIX is available in vials and 2 types of prefilled syringes. One type of prefilled syringe has a tip cap which may contain natural rubber latex. The other type has a tip cap and a rubber plunger which contain dry natural latex rubber. Use of these syringes may cause allergic reactions in latex sensitive individuals. The vial stopper does not contain latex.”
- *Description* Section 11 states: “HAVRIX is available in vials and 2 types of prefilled syringes. One type of prefilled syringe has a tip cap which may contain natural rubber latex. The other type has a tip cap and a rubber plunger which contain dry natural latex rubber. The vial stopper does not contain latex.”
- *How Supplied/Storage and Handling* Section 16 identifies which presentations contain latex.


GSK is working to produce updated Prescribing Information and cartons with appropriate latex-containing statements.

(continued on reverse)

The updated Prescribing Information can be found online at
<https://www.gsksource.com/gskprm/htdocs/documents/HAVRIX.PDF>.

In order for GSK to continue to monitor the safety of HAVRIX, we encourage healthcare professionals to report suspected adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (www.vaers.hhs.gov), or GSK at 1-888-825-5249. If you have any questions concerning medical or other issues, please contact the GSK Response Center at 1-888-825-5249.

Sincerely,



Leonard Friedland, MD
Vice President, Clinical and Medical Affairs, Vaccines, North America
GlaxoSmithKline Biologicals