



GlaxoSmithKline
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**INFORMATION RE: HIBERIX®
(HAEMOPHILUS B CONJUGATE VACCINE [TETANUS TOXOID CONJUGATE])
TIP CAPS OF THE PREFILLED DILUENT 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 diluent syringes supplied with HIBERIX may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals**. Please note that the Prescribing Information packaged in cartons of HIBERIX accompanied by this letter does not contain this information and is outdated. Revisions to the Prescribing Information are described below.

Updated Prescribing Information

The **outdated** Prescribing Information states that the tip caps of the needleless prefilled syringes do not contain latex and does not contain a warning that latex may cause allergic reactions in latex sensitive individuals.

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, Latex.”
- *Highlights of Prescribing Information – Warnings and Precautions* states: “The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.”
- *Warnings and Precautions Latex* Section 5.2 states: “The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.”
- *Description* Section 11 states: “The rubber plungers of the prefilled syringes and the vial stoppers do not contain latex.”
- *How Supplied/Storage and Handling* Section 16 states: HIBERIX is available as a vial (contains no latex) of lyophilized vaccine, accompanied by a prefilled TIP-LOK syringe (may contain latex) (packaged without needles) containing 0.7 mL of saline diluent. The tip caps of the needleless prefilled syringes may contain natural rubber latex.

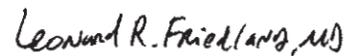
(continued on reverse)

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

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

In order for GSK to continue to monitor the safety of HIBERIX, 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,

A handwritten signature in black ink that reads "Leonard R. Friedland, MD". The signature is written in a cursive style.

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