



GlaxoSmithKline
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**INFORMATION RE: ENGERIX-B®
[HEPATITIS B VACCINE (RECOMBINANT)]**

**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 ENGERIX-B is supplied may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.** Please note that the cartons and Prescribing Information packaged in cartons of ENGERIX-B accompanied by this letter do not contain this information and are outdated.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The **outdated** Prescribing Information states that the tip caps of the prefilled syringes do not contain latex.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:

- *Description* Section states: “ENGERIX-B 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.”
- *Warnings* Section states: “ENGERIX B 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.”
- *How Supplied* Section identifies which presentations contain latex.


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

(continued on reverse)

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

In order for GSK to continue to monitor the safety of ENGERIX-B, 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