

Stability of *Engerix-B* When Stored Above Recommended Temperatures

This information is provided in response to your request for information about Engerix-B® [(Hepatitis B Vaccine (Recombinant))].

SUMMARY

- *Engerix-B* should be stored at temperatures ranging between 2°C - 8°C (36°F - 46°F).
- Based on in-house stability testing, *Engerix-B* has been shown to be stable (i.e., potency of the vaccine not affected) when left at temperatures above 46°F through 77°F (above 8°C through 25°C) for a maximum of 3 days (72 hours).
- Important safety information is found in the attached Prescribing Information.

Engerix-B should be stored at temperatures ranging between 2°C - 8°C (36°F - 46°F).

The following stability information pertains to a one-time excursion from the recommended storage temperatures noted above. Based on in-house stability testing, *Engerix-B* has been shown to be stable (i.e., potency of the vaccine not affected) when left at temperatures above 46°F through 77°F (above 8°C through 25°C) for a maximum of 3 days (72 hours).⁽¹⁾

Some information contained in this response is outside the approved Prescribing Information. This product is not approved for the use described. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling.

In order for GlaxoSmithKline to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 888-825-5249. Please consult the attached Prescribing Information.

This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

REFERENCE(S)

1. Data on File. EM2005/00062/00, 2005. *