

Notice to Readers: FDA Approval of an Alternate Dosing Schedule for a Combined Hepatitis A and B Vaccine (Twinrix®)



Weekly

October 12, 2007 / 56(40);1057

Persons using assistive technology might not be able to fully access information in this file. For assistance, please send e-mail to: mmwrq@cdc.gov. Type 508 Accommodation in the subject line of e-mail.

In April 2007, GlaxoSmithKline Vaccine Division (GlaxoSmithKline Biologicals, King of Prussia, Pennsylvania) received approval from the Food and Drug Administration (FDA) for an alternate schedule for Twinrix[®], a combined hepatitis A and hepatitis B vaccine. Twinrix was first licensed by FDA in 2001 on a 3-dose schedule (0, 1, and 6 months) for vaccination of persons aged ≥ 18 years (1). Using the newly licensed, alternate 4-dose schedule, Twinrix doses can be administered at 0, 7, and 21--30 days, followed by a dose at 12 months.

In immunogenicity studies among adults aged ≥ 18 years, the first 3 doses of the alternate schedule provided equivalent protection to the first 2 doses in the standard 3-dose Twinrix series (2). The first 3 doses of the alternate schedule also have proven effective in providing protection equivalent to a single dose of monovalent hepatitis A vaccine and to 2 doses of monovalent hepatitis B vaccine, administered using the licensed schedules for the monovalent vaccines (3). Thus, the alternate 4-dose schedule can be useful if vaccination with Twinrix has been initiated and travel or other potential exposure is anticipated before the second dose of Twinrix (or monovalent hepatitis B vaccine) is due, according to the standard 3-dose schedule (i.e., 1 month after the first dose). Additional information is available from the manufacturer's package insert (4) and GlaxoSmithKline Vaccines, telephone 800-366-8900.

References

1. CDC. FDA approval for a combined hepatitis A and B vaccine. *MMWR* 2001;50:806--7.
2. Joines RW, Blatter M, Abraham B, et al. A prospective, randomized, comparative US trial of a combination hepatitis A and B vaccine (Twinrix[®]) with corresponding monovalent vaccines (Havrix[®] and Engerix-B[®]) in adults. *Vaccine* 2001;19:4710--9.
3. Nothdurft HD, Dietrich M, Zuckerman JN, et al. A new accelerated vaccination schedule for rapid protection against hepatitis A and B. *Vaccine* 2002;20:1157--62.
4. GlaxoSmithKline. Revised package insert. Twinrix[®] (hepatitis A inactivated & hepatitis B [recombinant] vaccine). Available at <http://www.fda.gov/cber/label/hahbgsk032807lb.pdf>.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites. URL addresses listed in *MMWR* were current as of the date of publication.

Disclaimer All *MMWR* HTML versions of articles are electronic conversions from ASCII text into HTML. This conversion may have resulted in character translation or format errors in the HTML version. Users should not rely on this HTML document, but are referred to the electronic PDF version and/or the original *MMWR* paper copy for the official text, figures, and tables. An original paper copy of this issue can be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402-9371; telephone: (202) 512-1800. Contact GPO for current prices.

**Questions or messages regarding errors in formatting should be addressed to mmwrq@cdc.gov.

Date last reviewed: 10/11/2007