

Notice to Readers: FDA Approval of Havrix® (Hepatitis A Vaccine, Inactivated) for Persons Aged 1--18 Years



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On October 17, 2005, the Food and Drug Administration approved an application to allow use of the pediatric/adolescent formulation of Havrix[®] (hepatitis A vaccine, inactivated) (GlaxoSmithKline Biologicals, Rixensart, Belgium) for persons aged 1--18 years. Previously, pediatric use of Havrix was approved for use in persons aged 2--18 years.

Vaccine Description

The formulation, dosage, and schedule for Havrix were not changed. Each 0.5-mL dose of pediatric/adolescent Havrix contains 720 enzyme-linked immunosorbent assay units of formalin-inactivated hepatitis A viral antigen adsorbed onto aluminum hydroxide. The formulation contains 0.5% 2-phenoxyethanol as a preservative.

The pediatric/adolescent formulation of Havrix is indicated for vaccination of persons aged 1--18 years against disease caused by hepatitis A virus. Recommendations for hepatitis A vaccination have been published previously (1) and are periodically updated. The primary vaccination schedule is unchanged and consists of 2 doses, administered on a 0, 6--12-month schedule.

In a study presented as part of the labeling change application, 99% of 218 children aged 11--13 months and 100% of 200 children aged 15--18 months who received 2 doses of Havrix developed a vaccine response. The approval included concomitant use of Havrix with *Haemophilus influenzae* type b conjugate vaccine (PRP-T Hib). Data regarding concomitant use with other routinely recommended childhood vaccines are limited. According to general recommendations of the Advisory Committee on Immunization Practices, inactivated vaccines usually do not interfere with the immune response to other inactivated or live vaccines (2).

Among the 723 healthy children who received 1 or more dose of Havrix, the most common adverse events were similar among children aged 11--18 months and children aged 23--25 months. Havrix is contraindicated in persons with known hypersensitivity to any component of the vaccine. Additional information is available from the manufacturer's package insert and GlaxoSmithKline Biologicals at telephone 888-825-5249.

References

1. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1999;48(No. RR-12).
2. CDC. General recommendations on immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). *MMWR* 2002;51 (No. RR-2).

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