

Frequently asked questions on:

Hepatitis A vaccine

Q. Can a different brand of hepatitis A be used to complete a primary course?

A. Yes. Any current brand of hepatitis A vaccine can be used to boost another.

It is good practice to use the same brand of vaccine to complete a course. However, there may be occasions when this is not possible.

All hepatitis A vaccines are made from whole hepatitis A virus propagated in human diploid cells, although the final formulations of the vaccines differ.

Epaxal has been demonstrated to boost Havrix [1] and studies indicate that Havrix, Avaxim and Vaqta are interchangeable [2,3,4].

The SPC for Epaxal was amended in January 2005 to state that it can be used interchangeably with other inactivated hepatitis A vaccines for the first and second dose. (5)

References:

1. Beck BR, Hatz CFR, Loutan L, Steffen R. Immunogenicity of booster hepatitis A vaccine after primary immunization with an aluminium-adsorbed hepatitis A vaccine. *J Travel Med* 2004; 11:201-207
2. Sanofi Pasteur MSD and GlaxoSmithKline: Summary of Product Characteristics for Avaxim, Vaqta Paediatric and Havrix.
3. Clarke P, Kitchin N, Souverbie F. A randomised comparison of two inactivated hepatitis A vaccines, Avaxim and Vaqta, given as a booster to subjects primed with Avaxim. *Vaccine*. 2001; 19: 4429-4433
4. Zuckerman JN, Kirkpatrick CT, Huang M. Immunogenicity and reactogenicity of Avaxim (160 AU) as compared with Havrix (1440 EL.U) as a booster following primary immunization with Havrix (1440EL.U) against hepatitis A. *J Travel Med*. 1998; 5: 18-22
5. Instituto Sieroterapico Berna s.r.l. Summary of Product Characteristics for Epaxal. Revised 5 January 2005

Q. Does a course of hepatitis A vaccine need to be repeated if there has been a long interval between the first and second doses?

A. No. A primary course of hepatitis A vaccine does not need to be repeated.

An excellent immune response is obtained after a single dose of hepatitis A vaccine. In order to induce long-term immunity and protection, a second (booster) dose of vaccine should be given. The Summary of Product Characteristics (SPC) for all hepatitis A vaccines state that this second dose should optimally be given 6 to 12 months following the first dose of vaccine.

The SPC for Avaxim states that the second dose may be administered up to 36 months following the first [1].

The SPC for Havrix Monodose states that if the second, booster dose of vaccine is delayed up to 3 years after the primary dose, antibody levels are produced that are similar to those following a booster dose administered within the recommended time interval [2].

The SPC for Epaxal states that the second dose may be given up to 4 years following the first dose, based on experience in adult travellers [3].

Although booster doses delayed beyond the recommended intervals described above are not covered by the product licence, research indicates that a second dose given at long intervals will still result in a boosting immune response [4, 5, 6, 7]. A second dose of Havrix given up to 8 years after the first dose boosted the primary dose [4, 6]. Good protective antibody levels have also been achieved when the second dose of Epaxal was given up to 56 months after the primary dose [5].

Thus, based on evidence from available studies, there is no interval which would require restarting a course of hepatitis A vaccine.

References:

1. Sanofi Pasteur MSD. Summary of Product Characteristics for Avaxim, revised June 2004.
2. GlaxoSmithKline. Summary of Product Characteristics for Havrix Monodose, revised 25 June 2002.
3. Instituto Sieroterapico Berna s.r.l. Summary of Product Characteristics for Epaxal. Revised 5 January 2005.
4. Landry P, Tremblay S, Darioli R, Genton B. Inactivated hepatitis A vaccine booster given \geq 24 months after primary dose. *Vaccine*. 2001; 19: 399-402.
5. Beck B, Hatz C, Broennimann R et al. Immunogenicity of two doses of a virosome formulated hepatitis A vaccine administered 18 to 56 months apart (abstract) *Clin Microbiol Infect*. 2000; 6 (suppl 10:We07).
6. Iwarson S, Lindh M and Widerstrom L. Excellent booster response 4 to 8 years after a single primary dose of an inactivated hepatitis A vaccine. *J Travel Med* 2004;11:120-121.
7. Van Damme P, Banatvala J, Fay O, et al. Hepatitis A booster vaccination: is there a need? *Lancet* 2003;362:1065-1071.

Q. Is there a need for doses of hepatitis A vaccines after the two dose schedule has been completed?

A. Not at the present. A 20 year duration of protection has been accepted by the Joint Committee on Vaccination and Immunisation (JCVI), however, protection may be lifelong following 2 doses of vaccine in immunologically normal hosts.

The SPC for Havrix Monodose and Avaxim state that the booster dose of hepatitis A vaccine will elicit protective antibodies that are expected to persist for at least 10 years [1,2].

The SPC for Epaxal states that mathematical models suggest that protection will persist for at least 20 years in the majority of vaccinees [3].

Anti-hepatitis A antibodies, which are considered a marker for protection against hepatitis A, have been demonstrated for up to 12 years in adults and 5 years in children [4, 5]. Different mathematical models based on different vaccine products have consistently predicted titres to last for ≥ 20 years [6]. Some have predicted antibody persistence up to 55 years [7].

It can also be expected that exposure to hepatitis A virus will induce an amnestic protective response following a primary course of hepatitis A vaccine.

In summary, there is no need to provide a booster dose of vaccine following a primary series of hepatitis A vaccine in immune competent children and adults. The duration of protection from the primary series can be expected to be at least 20 years and probably indefinite.

References:

1. Sanofi Pasteur MSD. Summary of Product Characteristics for Avaxim, revised June 2004
2. GlaxoSmithKline. Summary of Product Characteristics for Havrix Monodose, revised 25 June 2002
3. Instituto Sieroterapico Berna s.r.l. Summary of Product Characteristics for Epaxal. Revised 5 January 2005.
4. 1. Van Herck K, Van Damme P, Lievens M and Stoffel M. Hepatitis A vaccine: indirect evidence of immune memory 12 years after the primary course. *J Med Virol* 2004;72:194-196.
5. 1. Fan PC, Chang MH, Lee PI, et al. Follow-up immunogenicity of an inactivated hepatitis A virus vaccine in healthy children: results after 5 years. *Vaccine* 1998;16:232-235.
6. Van Damme P, Banatvala J, Fay O et al. Hepatitis A booster vaccination: is there a need? *Lancet*. 2003; 362: 1065-1071
7. Bovier PA, Bock J, Loutan L et al. Long-term immunogenicity of an inactivated virosome hepatitis A vaccine. *J Med Virol*. 2002;68:489-93.