Interchangeability of HEPLISAV-B With Other Hepatitis B Vaccines

Your inquiry concerned the use of HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] and its interchangeability with other approved hepatitis B vaccines.

HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older.

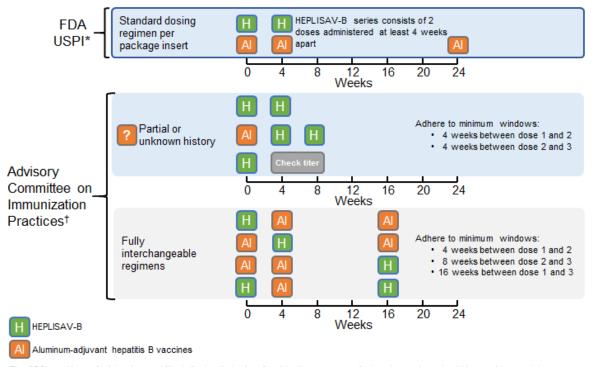
In a publication by Schillie (2018), the Center for Disease Control's (CDC) guidance for interchangeability and dosing schedule was presented. The CDC noted that data are limited on the safety and immunogenicity effects when HEPLISAV-B is interchanged with hepatitis B vaccines from other manufacturers. The CDC's guidance indicated that when feasible, the same manufacturer's vaccines should be used to complete the series. However, vaccination should not be deferred when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable.

The 2-dose HEPLISAV-B vaccine series only applies when both doses in the series consist of HEPLISAV-B. Series consisting of a combination of 1 dose of HEPLISAV-B and a vaccine from a different manufacturer should consist of 3 total vaccine doses and should adhere to the 3-dose schedule minimum intervals of 4 weeks between dose 1 and 2, 8 weeks between dose 2 and 3, and 16 weeks between dose 1 and 3. However, a series containing 2 doses of HEPLISAV-B administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer. Doses administered at less than the minimum interval should be repeated.

Figure 1 depicts the various scenarios in which HEPLISAV-B may be interchanged with a manufacturer of aluminum adjuvant hepatitis B vaccine to complete a dosing regimen.

Figure 1: Interchangeability of HEPLISAV-B with a manufacturer of aluminum adjuvant hepatitis B vaccine to complete a dosing regimen.

Interchangeability of HEPLISAV-B and Aluminum-adjuvant Hepatitis B Vaccines



The CDC's guidance for interchangeability indicates that when feasible, the same manufacturer's vaccines should be used to complete a hepatitis B series. A 2-dose HEPLISAV-B vaccine series only applies when both doses in the series consist of HEPLISAV-B. A dosing regimen consisting of 2 different vaccine products should consist of a total of 3 doses in the possible combinations shown here. Doses administered at less than the minimal interval should be repeated.

USPI = United States prescribing information.

*HEPLISAV-B [package insert]. Berkeley, CA: Dynavax Technologies Corporation; 2018.

†Schille S, et al. MMWR Morb Mortal Wkly Rep. 2018;67:455-458.

References:

HEPLISAV-B [package insert]. Berkeley, CA: Dynavax Technologies Corporation; 2017.

Schillie S, Harris A, Link-Gelles, R, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No.15);455-8.