# Hepatitis B Vaccine ENGERIX®-B

Supplier: GlaxoSmithKline Inc.

(Adult presentation: 20 mcg/1 mL, Pediatric presentation: 10 mcg/0.5 mL)

### **INDICATIONS:**

- See Hepatitis B Vaccine Pre-Exposure Indications.
- See Hepatitis B Vaccine Post-Exposure Indications.
- Infants and children who are not receiving hepatitis B vaccine as a combination product in INFANRIX hexa® as part of the routine schedule.

# DOSES AND SCHEDULE: A, B

<u>High risk infants</u>: <sup>c</sup> 1 dose given as 0.5 mL (10 mcg) **IM** at birth, followed by INFANRIX hexa® at 2, 4 and 6 months of age. <sup>D</sup>

Infants and children who are not receiving INFANRIX hexa® as part of the routine schedule: 3 doses given as 0.5 mL (10 mcg) **IM** at 2, 4, and 6 months of age. <sup>D</sup>

Children and adolescents not immunized in infancy:

- Children less than 11 years of age and adolescents 16-19 years of age (inclusive): 3
  doses given as 0.5 mL (10 mcg) IM at 0, 1 and 6 months.
- Adolescents 11-15 years of age (inclusive): E 2 doses given as 1.0 mL (20 mcg) IM at 0 and 6 months.

Eligible adults 20 years of age and older: 3 doses given as 1.0 mL (20 mcg) **IM** at 0, 1 and 6 months.

#### **ADMINISTRATION:**

No additional requirements.

## **BOOSTER DOSES:**

Booster doses and/or re-immunization may be recommended for certain special populations; see <a href="Communicable Disease Control Manual">Communicable Disease Control Manual</a>, <a href="Chapter 1">Chapter 1</a>: Hepatitis B, 5.2 Post-vaccination serology follow-up: boosters and re-immunization recommendations.

<sup>&</sup>lt;sup>A</sup> Clients with chronic kidney disease require a specific hepatitis B vaccine dosage and series (see Hepatitis B Vaccine Program for Chronic Kidney Disease Clients).

B Individuals with the following immunocompromising conditions require the <u>Hepatitis B Vaccine Higher</u> <u>Dose Schedule</u>: congenital immunodeficiency, hematopoietic stem cell transplant recipients, solid organ transplant candidates/recipients and HIV infection.

<sup>&</sup>lt;sup>c</sup> High risk infants as outlined in <u>Hepatitis B Vaccine Post-Exposure Indications</u>.

<sup>&</sup>lt;sup>D</sup> Infants who have received doses of hepatitis B vaccine at birth and 1 month of age should receive a 3<sup>rd</sup> dose at 6 months of age. Infants weighing less than 2000 grams at birth who received doses on a 0, 1 and 6 month schedule will require a 4<sup>th</sup> dose of hepatitis B vaccine at 8 months of age.

<sup>&</sup>lt;sup>E</sup> A minimum age of 10 years and 8 months may be used for catch-up of grade 6 students for operational purposes.

F A 3-dose schedule given as 0.5 mL (10 mcg) IM at 0, 1 and 6 months can be used if appropriate.

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# **SEROLOGICAL TESTING:**

Post-immunization serologic testing is not recommended after receiving hepatitis B-containing vaccine in routine programs. However, it is recommended for certain special populations: see Communicable Disease Control Manual, Chapter 1: Hepatitis B, 4.5 Post-vaccination Serology.

# **CONTRAINDICATIONS:**

1. History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of ENGERIX®-B.

## **PRODUCT COMPONENTS:**

Potential allergens: yeast protein.

Other components: aluminum hydroxide, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate.

### PRECAUTIONS:

Not applicable.

### **SPECIAL CONSIDERATIONS:**

- ENGERIX®-B and RECOMBIVAX HB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the respective product. There must be a minimum of 24 weeks between doses 1 and 2 whenever both products are used in a 2-dose series.
- If the immunization series is interrupted after the 1<sup>st</sup> dose, the 2<sup>nd</sup> dose should be administered as soon as possible. If only the 3<sup>rd</sup> dose is delayed, administer as soon as possible. If years have lapsed between the 1<sup>st</sup> and 2<sup>nd</sup> dose, it may be prudent to assess antibody response post-series, especially if the client is at significant risk.

# **ADVERSE EVENTS:**

Local: pain, redness, swelling.

**Systemic:** fever, headache, nausea, diarrhea, fatigue, malaise.