Merck & Co., Inc.
351 Sumneytown Pike
North Wales, PA 19454

March 9, 2020

Dear Health Care Professional,

RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)] (Pediatric Formulation) is Available

Merck is pleased to announce the return of RECOMBIVAX HB (Pediatric Formulation) to its vaccine portfolio through the commercial channel. Since mid-2017, Merck's limited supply has been allocated to the CDC to ensure utilization was consistent with their clinical guidance. Beginning on March 9, 2020, RECOMBIVAX HB (Pediatric Formulation) will be available for ordering from Merck authorized wholesalers, distributors, or directly from Merck. Products will also begin to ship starting March 9, 2020.

The price for RECOMBIVAX HB (Pediatric Formulation) may vary from the catalog price, depending, for example, on how a customer purchases the product, the availability of discounts, and wholesaler/distributor, or other charges. Please refer to any Terms and Conditions and/or agreements you may have for questions related to pricing.

Product Description	NDC Number	Package
RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)] — Pediatric Formulation	NDC 0006-4093-02	ten (10) 5 mcg/0.5 mL single-dose pre-filled Luer-Lok® syringes with tip caps
RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)] — Pediatric Formulation	NDC 0006-4981-00	5 mcg/0.5 mL - 10 single-dose 0.5 mL vials

Other formulations of RECOMBIVAX HB remain temporarily out of stock. Current information on supply status can be found on the Supply Status page at merckvaccines.com®. You can opt-in to receive an email with supply status updates for all Merck vaccines, so that you have current information about when the product is expected to be available.

About RECOMBIVAX HB

Indications

RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)] is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB is approved for use in individuals of all ages.

Selected Safety Information for RECOMBIVAX HB

Do not administer RECOMBIVAX HB to individuals with a history of severe allergic or hypersensitivity reactions (eg, anaphylaxis) after a previous dose of any hepatitis B-containing vaccine or to any component of RECOMBIVAX HB, including yeast.

The vial stopper and the syringe plunger stopper and tip cap contain dry natural latex rubber, which may cause allergic reactions in latex-sensitive individuals.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including RECOMBIVAX HB, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. For RECOMBIVAX HB, this assessment should include consideration of the mother's hepatitis B antigen status and high probability of maternal transmission of hepatitis B virus to infants born to mothers who are HBsAg positive if vaccination is delayed.

Hepatitis B vaccination should be delayed until 1 month of age or hospital discharge in infants weighing <2000 g if the mother is documented to be HBsAg negative at the time of the infant's birth. Infants weighing <2000 g born to HBsAg positive or HBsAg unknown mothers should receive vaccine and hepatitis B immune globulin (HBIG) in accordance with the Advisory Committee on Immunization Practices (ACIP) recommendations if HBsAg status cannot be determined.

Hepatitis B virus has a long incubation period. RECOMBIVAX HB may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccination.

Vaccination with RECOMBIVAX HB may not protect all individuals.

In healthy infants and children (up to 10 years of age), injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. In a study that compared the 3-dose regimen (5 mcg) with the 2-dose regimen (10 mcg) of RECOMBIVAX HB in adolescents, the overall frequency of adverse reactions was generally similar.

Additional adverse reactions have been reported with the use of the marketed vaccine. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure.

The duration of the protective effect on RECOMBIVAX HB in healthy vaccinees is unknown at present and the need for booster doses is not yet defined.

RECOMBIVAX HB should be administered as soon as possible after being removed from refrigeration.

Refer to recommendations of the Advisory Committee on Immunization Practices (ACIP) and to the package insert for HBIG for management of persons with known or presumed exposure to the hepatitis B virus (eg, neonates born of infected mothers or persons who experienced percutaneous or permucosal exposure to the virus). When recommended, administer RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)] and HBIG intramuscularly at separate sites (eg, opposite anterolateral thighs for exposed neonates) as soon as possible after exposure.

Before administering RECOMBIVAX HB, please read the accompanying Prescribing Information.

For additional copies of the Prescribing Information, call 1-800-672-6372, visit merckvaccines.com, or contact your Merck representative.

When you order Merck vaccines, remember to order RECOMBIVAX HB. We thank you for your business and commitment to Merck Vaccines.

If you have any questions, please contact your Merck account representative or call the Merck Vaccine Customer Center at 877-VAX-MERCK (877-829-6372).

Sincerely,

Merck Professional Services