HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RECOMBIVAX HB safely and effectively. See full prescribing information for RECOMBIVAX HB.

RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant)
Suspension for intramuscular injection
Initial U.S. Approval: 1986

----------RECENT MAJOR CHANGES----------
Dosage and Administration (2) 12/2018

----------INDICATIONS AND USAGE----------
RECOMBIVAX HB is a vaccine 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. RECOMBIVAX HB Dialysis Formulation is approved for use in predialysis and dialysis patients 18 years of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
RECOMBIVAX HB
- Persons from birth through 19 years of age: A series of 3 doses (0.5 mL each) given on a 0-, 1-, and 6-month schedule. (2.1)
- Adolescents 11 through 15 years of age: A series of either 3 doses (0.5 mL each) given on a 0-, 1-, and 6-month schedule or a series of 2 doses (1.0 mL) on a 0- and 4- to 6-month schedule). (2.1)
- Persons 20 years of age and older: A series of 3 doses (1.0 mL each) given on a 0-, 1-, and 6-month schedule. (2.1)

RECOMBIVAX HB Dialysis Formulation
- Adults on predialysis or dialysis: A series of 3 doses (1.0 mL each) given on a 0-, 1-, and 6-month schedule. (2.1)

---------- DOSAGE FORMS AND STRENGTHS ----------
RECOMBIVAX HB is a sterile suspension available in the following presentations:
- 0.5 mL (5 mcg) Pediatric/Adolescent Formulation single-dose vials and prefilled syringes (3, 11, 16.1)
- 1 mL (10 mcg) Adult Formulation single-dose vials and prefilled syringes (3, 11, 16.1)

RECOMBIVAX HB Dialysis Formulation is a sterile suspension available in the following presentation:
- 1 mL (40 mcg) single-dose vials (3, 11, 16.1)

----------CONTRAINDICATIONS----------
Severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a previous dose of any hepatitis B-containing vaccine, or to any component of RECOMBIVAX HB, including yeast. (4, 11)

---------- WARNINGS AND PRECAUTIONS ----------

The vial stopper, the syringe plunger stopper, and tip cap contain dry natural latex rubber which may cause allergic reactions in latex-sensitive individuals. (5.1)

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. (5.2)

---------- ADVERSE REACTIONS ----------
In healthy infants and children (up to 10 years of age), the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. (6.1)
In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------
Do not mix RECOMBIVAX HB with any other vaccine in the same syringe or vial. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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