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BRIEF SUMMARY

RECOMBIVAX HB®
HEPATITIS B VACCINE (RECOMBINANT)

Please read the full Prescribing Information for complete details.

INDICATIONS AND USAGE

RECOMBIVAX HB is indicated for vaccination against infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB Dialysate Formulation is indicated for vaccination of adult predialysis and dialysis patients against infection caused by all known subtypes of hepatitis B virus.

CONTRAINDICATIONS

Hypersensitivity to yeast or any component of the vaccine.

WARNINGS

Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine (see CONTRAINDICATIONS).

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis B in such patients.

PRECAUTIONS

General

As with any percutaneous vaccine, epinephrine should be available for immediate use should an anaphylactoid reaction occur.

Any serious adverse infection is reason for delaying use of the vaccine except when in the opinion of the physician, withholding the vaccine entails a greater risk. Caution and appropriate care should be exercised in administering the vaccine to individuals with severely compromised cardiac pulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with the vaccine. It is also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The vaccine should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether the vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the vaccine is administered to a nursing woman.

Pediatric Use

RECOMBIVAX HB has been shown to be usually well-tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well; maternally transferred antibodies do not interfere with the active immune response to the vaccine. See DOSAGE AND ADMINISTRATION in full Prescribing Information for recommended pediatric dosage and for recommended dosage for infants born to HBsAg positive mothers.

The safety and effectiveness of RECOMBIVAX HB Dialysate Formulation in children have not been established.

ADVERSE REACTIONS

RECOMBIVAX HB and RECOMBIVAX HB Dialysate Formulation are generally well-tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No adverse experiences were reported during clinical trials which could be related to changes in the titers of antibodies to yeast. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

In a group of studies, 1038 doses of RECOMBIVAX HB were administered to 653 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. Injection site reactions (including erythema and swelling) and systemic complaints were reported following 8% and 17% of the injections, respectively. The most frequently reported systemic adverse reactions (≥ 1% injections), in decreasing order of frequency were irritability, fever (> 101°F oral equivalent), crying, diarrhea, vomiting, diminished appetite, and insomnia.

In a group of studies, 2568 doses of RECOMBIVAX HB were administered to 1252 healthy adults who were monitored for 5 days after each dose. Injection site and systemic complaints were reported following 17% and 15% of the injections, respectively. The following adverse reactions were reported:

Incidence Equal to or Greater Than 1% of Injections

LOCAL REACTION (INJECTION SITE):
Injection site reactions consisting principally of soreness, and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, and nodule formation.

BODY AS A WHOLE

The most frequent systemic complaints include fatigue/weakness; headache; fever (> 101°F); and malaise.

DIGESTIVE SYSTEM

Nausea; and diarrhea

RESPIRATORY SYSTEM

Pharyngitis; and upper respiratory infection

Incidence Less Than 1% of Injections

BODY AS A WHOLE

Sweating; achiness; sensation of warmth; lightheadedness; chills; and flushing

DIGESTIVE SYSTEM

Vomiting; abdominal pain/ cramps; dyspepsia; and diminished appetite

RESPIRATORY SYSTEM

Rhinitis; influenza; and cough

NERVOUS SYSTEM

Vertigo/dizziness; and paresthesia

INTEGUMENTARY SYSTEM

Pruritus; rash (non-specific); angioedema; and urticaria

MUSCULOSKELETAL SYSTEM

Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; and neck stiffness

HEMOLYTIC/HEMATOLOGIC SYSTEM

Anemia

PSYCHIATRIC/BEHAVIORAL

Insomnia/disturbed sleep

SPECIAL SENSES

Earache

UROGENITAL SYSTEM

Dysuria

CARDIOVASCULAR SYSTEM

Hypotension

Marketing Experience

The following additional adverse reactions have been reported with use of the marketed vaccine. In many instances, the relationship to the vaccine was unclear.

Hypersensitivity

Anaphylaxis and symptoms of immediate hypersensitivity reactions including rash, pruritus, urticaria, edema, angioedema, dyspnea, chest discomfort, bronchial spasm, palpitation, or symptoms consistent with a hypertensive episode have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including; arthralgia/ arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum (see WARNINGS and PRECAUTIONS).

Digestive System

Elevation of liver enzymes; constipation.

Nervous System

Guillain-Barré Syndrome; multiple sclerosis; myelitis including transverse myelitis; peripheral neuropathy including Bell’s Palsy; radiculopathy; herpes zoster; migraine; muscle weakness; hypotension.

Integumentary System

Stevens-Johnson Syndrome; petechiae.

Musculoskeletal System

Arthritis.

Hematologic

Increased erythrocyte sedimentation rate; thrombocytopenia.

Immune System

Lupus-like syndrome.

Psychiatric/Behavioral

Irritability; agitation; somnolence.

Special Senses

Optic neuritis; tinnitus; conjunctivitis; visual disturbances.

Cardiovascular System

Syncope, tachycardia.

The following adverse reaction has been reported with another Hepatitis B Vaccine (Recombinant) but not with RECOMBIVAX HB: keratitis.
In Your Adult Predialysis and Dialysis Patients...

HELP ERADICATE HEPATITIS B

Use the only vaccine with a concentrated 40 mcg/mL dose precisely formulated for predialysis and dialysis patients

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RECOMBIVAX HB is contraindicated in the presence of hypersensitivity to yeast or to any component of the vaccine. Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine. RECOMBIVAX HB Dialysis Formulation (40 mcg/mL) is intended only for adult predialysis/dialysis patients.

A booster dose or revaccination may be considered if the anti-HBs level is less than 10 mIU/mL 1–2 months after the third dose.

Please read the Brief Summary of the Prescribing Information accompanying this advertisement.