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EDITORIAL

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What is it?

Spread by blood or sexual contact.

300,000 new cases will occur in the U. S. this year.

Hemophiliacs, Asian immigrants, heterosexuals with multiple partners, male homosexuals, IV drug users, and health-care personnel are at highest risk.

See the following page for a Brief Summary of Prescribing Information for RECOMBIVAX HB" (Hepatitis B Vaccine [Recombinant], MSD).

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MSD

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SHARP&
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RECOMBIVAX HB®
[Hepatitis B Vaccine (Recombinant), MSD]

INDICATIONS AND USAGE

RECOMBIVAX HB is indicated for immunization against infection caused by all known subtypes of hepatitis B virus.

RECOMBIVAX HB will not prevent hepatitis caused by other agents, such as hepatitis A virus, non-A, non-B hepatitis viruses, or other viruses known to infect the liver.

Vaccination is recommended in persons of all ages who are or will be at increased risk of infection with hepatitis B virus. In areas with high prevalence of infection, most of the population are at risk of acquiring hepatitis B infection at a young age. Therefore, vaccination should be targeted to prevent such transmission. In areas of low prevalence, vaccination should be limited to those who are in groups identified as being at increased risk of infection.

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 RECOMBIVAX HB (see CONTRAINDICATIONS).

RECOMBIVAX HB®
[Hepatitis B Vaccine (Recombinant), MSD]

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time RECOMBIVAX HB is given. RECOMBIVAX HB 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 active infection is reason for delaying use of RECOMBIVAX HB except when, in the opinion of the physician, withholding the vaccine entails a greater risk.

Caution and appropriate care should be exercised in administering RECOMBIVAX HB to individuals with severely compromised cardiopulmonary 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 RECOMBIVAX HB. It is also not known whether RECOMBIVAX HB can cause fetal harm when administered to a pregnant woman or can affect

RECOMBIVAX HB®
[Hepatitis B Vaccine (Recombinant), MSD]

reproduction capacity. RECOMBIVAX HB should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether RECOMBIVAX HB is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RECOMBIVAX HB 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 for recommended pediatric dosage and for recommended dosage for infants born to HBsAg positive mothers.

ADVERSE REACTIONS

RECOMBIVAX HB is generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No serious hypersensitivity reactions have been reported. No adverse experiences

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[Hepatitis B Vaccine (Recombinant), MSD]

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, 3258 doses of vaccine 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 [≥100°F], malaise.

DIGESTIVE SYSTEM

Nausea; diarrhea.

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Hepatitis B.

It can be prevented.

A vaccine is available.

Help eliminate the **risk...**

Recombivax HB®

(Hepatitis B Vaccine [Recombinant] / MSD)

RECOMBIVAX HB is contraindicated in the presence of hypersensitivity to yeast or any other component of the vaccine.

See below for a Brief Summary of Prescribing Information for RECOMBIVAX HB.

RECOMBIVAX HB®
[Hepatitis B Vaccine (Recombinant), MSD]

RESPIRATORY SYSTEM
Pharyngitis; upper respiratory infection.

Incidence Less than 1% of Injections

BODY AS A WHOLE
Sweating; achiness; sensation of warmth; lightheadedness; chills; flushing.

DIGESTIVE SYSTEM
Vomiting, abdominal pains/cramps; dyspepsia; diminished appetite

RESPIRATORY SYSTEM
Rhinitis; influenza; cough.

NERVOUS SYSTEM
Vertigo/dizziness; paresthesia.

INTEGUMENTARY SYSTEM
Pruritus; rash [non-specified]; angioedema; urticaria.

MUSCULOSKELETAL SYSTEM
Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffness.

HEMIC/LYMPHATIC SYSTEM
Lymphadenopathy.

PSYCHIATRIC/BEHAVIORAL
Insomnia/disturbed sleep.

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[Hepatitis B Vaccine (Recombinant), MSD]

SPECIAL SENSES
Earache.

UROGENITAL SYSTEM
Dysuria.

CARDIOVASCULAR SYSTEM
Hypotension.

Potential ADVERSE EFFECTS

In addition, a variety of adverse effects, not observed in clinical trials with RECOMBIVAX HB, have been reported with HEPTAVAX-B® [Hepatitis B Vaccine, MSD] (plasma-derived hepatitis B vaccine). Those listed below are to serve as alerting information to physicians:

Hypersensitivity: An apparent hypersensitivity syndrome of delayed onset has been reported days to weeks after vaccination. This has included the following findings: arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, or ecchymoses.

Nervous System: Neurological disorders such as optic neuritis, myelitis including transverse myelitis, acute radiculoneuropathy including Guillain-Barré syndrome, peripheral neuropathy including Bell's palsy and herpes zoster.

Hematologic: Thrombocytopenia.

RECOMBIVAX HB®
[Hepatitis B Vaccine (Recombinant), MSD]

Special Senses: Tinnitus; visual disturbances.

DOSAGE AND ADMINISTRATION

Do not inject intravenously or intradermally.

RECOMBIVAX HB is for intramuscular injection. The deltoid muscle is the preferred site for intramuscular injection in adults. Data suggest that injections given in the buttocks frequently are given into fatty tissue instead of into muscle. Such injections have resulted in a lower seroconversion rate than was expected. The anterolateral thigh is the recommended site for intramuscular injection in infants and young children.

RECOMBIVAX HB may be administered subcutaneously to persons at risk of hemorrhage following intramuscular injections. However, when other aluminum-adsorbed vaccines have been administered subcutaneously, an increased incidence of local reactions including subcutaneous nodules has been observed. Therefore, subcutaneous administration should be used only in persons [e.g., hemophiliacs] at risk of hemorrhage following intramuscular injections.

The immunization regimen consists of 3 doses of vaccine. The volume of vaccine to be given on each occasion is as follows:

RECOMBIVAX HB®
[Hepatitis B Vaccine (Recombinant), MSD]

Group	Formulation	Initial	1 month	6 months
Younger Children [Birth to 10 years of age]	Pediatric 5 mcg/0.5 mL	0.5 mL	0.5 mL	0.5 mL
Adults and Older Children	Adult 10 mcg/1.0 mL	1.0 mL	1.0 mL	1.0 mL

Whenever revaccination or administration of a booster dose is appropriate, RECOMBIVAX HB may be used.

For dosage for infants born of HBsAg positive mothers and for dosage for known or presumed exposure to HBsAg, see the Prescribing Information.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

Storage

Store vials at 2–8°C (35.6–46.4°F). Storage above or below the recommended temperature may reduce potency.

Do not freeze since freezing destroys potency.

For more detailed information, consult your MSD Representative or see Prescribing Information. Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486. **J7RX04 (201)**

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