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Vaccination is the best way to prevent hepatitis B virus (HBV) infection.Hepatitis B vaccine is safe and effective.All pregnant women who are at risk for HBV infection and have not been vaccinated previously should be vaccinated.Beginning at birth, all infants should receive the hepatitis B vaccine series. Hepatitis B vaccines are available as a single-antigen formulation and in combination with other vaccines. All hepatitis B vaccines contain yeast protein and aluminum adjuvant. For pregnant women, after initial hepatitis B surface antigen (HBsAg) screen is drawn for current pregnancy, initiate vaccine series with Engerix-B, Recombivax-HB, or Twinrix for those who have not previously been vaccinated. The two single-antigen vaccines, Engerix-B and Recombivax-HB, can be used starting at birth. CDC recommends that all infants receive a dose of the hepatitis B vaccine at birth. All infants should receive a dose of hepatitis B vaccine at birth regardless of the HBV infection status of the birth parent. This birth dose, along with hepatitis B immune globulin (HBIG), serves as postexposure immunoprophylaxis for infants born to a parent with HBV infection. TABLE 3. Hepatitis B vaccine schedules for infants, by infant birthweight and maternal HBsAg status Birthweight Maternal HBsAg status Single-antigen vaccine Single-antigen + combination vaccine Dose Age Dose Age 2,000 g Positive 1 Birth (12 hrs) 1 Birth (12 hrs) HBIG Birth (12 hrs) HBIG Birth (12 hrs) 2 12 mos 2 2 mos 3 6 mos 3 4 mos 4 6 mos Unknown* 1 Birth (12 hrs) 1 Birth (12 hrs) 2 12 mos 2 2 mos 3 6 mos 3 4 mos 4 6 mos Negative 1 Birth (24 hrs) 1 Birth (24 hrs) 2 12 mos 2 2 mos 3 618 mos 3 4 mos 4 6 mos 1% injections), in decreasing order of frequency, were irritability, fever (101F oral equivalent), diarrhea, fatigue/weakness, diminished appetite, and rhinitis.In a study that compared the three-dose regimen (5 mcg) with the two-dose regimen (10 mcg) of RECOMBIVAX HB in adolescents, the overall frequency of adverse reactions was generally similar.In a group of studies, 3258 doses of RECOMBIVAX HB, 10 mcg, were administered to 1252 healthy adults who were monitored for 5 days after each dose. Injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively. The following adverse reactions were reported:Incidence Equal To or Greater Than 1% of InjectionsGENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONSInjection site reactions consisting principally of soreness, and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, nodule formation.The most frequent systemic complaints include fatigue/weakness; headache; fever (100F); malaise.GASTROINTESTINAL DISORDERSNausea; diarrheaRESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS Pharyngitis; upper respiratory infectionIncidence Less Than 1% of InjectionsGENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONSSweating; achiness; sensation of warmth; lightheadedness; chills; flushingGASTROINTESTINAL DISORDERSVomiting; abdominal pains/cramps; dyspepsia; diminished appetiteRESPIRATORY, THORACIC AND MEDIASTINAL DISORDERSRhinitis; influenza; coughNERVOUS SYSTEM DISORDERSVertigo/dizziness; paresthesiaSKIN AND SUBCUTANEOUS TISSUE DISORDERSPruritus; rash (non-specified); angioedema; urticariaMUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERSArthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffnessBLOOD AND LYMPHATIC DISORDERSLymphadenopathyPSYCHIATRIC DISORDERSInsomnia/disturbed sleepEAR AND LABYRINTH DISORDERSEaracheRENAL AND URINARY DISORDERSDysuriaCARDIAC DISORDERSHypotension 6.2Post-Marketing ExperienceThe following additional adverse reactions have been reported with 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.Immune System DisordersHypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria 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 (5.1)]. Autoimmune diseases including systemic lupus erythematosus (SLE), lupus-like syndrome, vasculitis, and polyarteritis nodosa have also been reported.Gastrointestinal DisordersElevation of liver enzymes; constipationNervous System DisordersGuillain-Barr syndrome; multiple sclerosis; exacerbation of multiple sclerosis; myelitis including transverse myelitis; seizure; febrile seizure; peripheral neuropathy including Bell's Palsy; radiculopathy; herpes zoster; migraine; muscle weakness; hypesthesia; encephalitisSkin and Subcutaneous DisordersStevens-Johnson syndrome; alopecia; petechiae; eczemaMusculoskeletal and Connective Tissue DisordersArthritisPain in extremityBlood and Lymphatic System DisordersIncreased erythrocyte sedimentation rate; thrombocytopeniaPsychiatric DisordersIrritability; agitation; somnolenceEye DisordersOptic neuritis; tinnitus; conjunctivitis; visual disturbances; uveitisCardiac DisordersSyncope; tachycardiaThe following adverse reaction has been reported with another Hepatitis B Vaccine (Recombinant) but not with RECOMBIVAX HB: keratitis. 7 DRUG INTERACTIONS 7.1Concomitant Administration with Other VaccinesDo not mix RECOMBIVAX HB with any other vaccine in the same syringe or vial. Use separate injection sites and syringes for each vaccine. In clinical trials in children, RECOMBIVAX HB was concomitantly administered with one or more of the following US licensed vaccines: Diphtheria, Tetanus and whole cell Pertussis; oral Poliomyelitis vaccine; Measles, Mumps, and Rubella Virus Vaccine, Live; Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] or a booster dose of Diphtheria, Tetanus, acellular Pertussis. Safety and immunogenicity were similar for concomitantly administered vaccines compared to separately administered vaccines. In another clinical trial, a related HBsAg-containing product, Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) combination product (no longer licensed), was given concomitantly with eIPV (enhanced inactivated Poliovirus vaccine) or VARIVAX [Varicella Virus Vaccine Live (Oka/Merck)], using separate sites and syringes for injectable vaccines. No serious vaccine-related adverse events were reported, and no impairment of immune response to these individually tested vaccine antigens was demonstrated. The Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) combination product (no longer licensed) has also been administered concomitantly with the primary series of DTaP to a limited number of infants. No serious vaccine-related adverse events were reported. 7.2Concomitant Administration with Immune GlobulinRECOMBIVAX HB may be administered concomitantly with HBIG. The first dose of RECOMBIVAX HB may be given at the same time as HBIG, but the injections should be administered at different sites. 7.3Interference with Laboratory TestsHepatitis B surface antigen (HBsAg) derived from hepatitis B vaccines has been transiently detected in blood samples following vaccination. Serum HBsAg detection may not have diagnostic value within 28 days after receipt of a hepatitis B vaccine, including RECOMBIVAX HB. 8 USE IN SPECIFIC POPULATIONS 8.1 PregnancyRisk SummaryAll pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4%, and 15% to 20%, respectively.There are no adequate and well-controlled studies designed to evaluate RECOMBIVAX HB in pregnant women. Available post-approval data do not suggest an increased risk of miscarriage or major birth defects in women who received RECOMBIVAX HB during pregnancy.Developmental toxicity studies have not been conducted with the vaccine in animals.DataHuman DataIn post-licensure clinical studies of RECOMBIVAX HB, 26 pregnant women were inadvertently administered RECOMBIVAX HB following their last menstrual period. Among these pregnancies, after excluding elective terminations (n=3), there were 23 pregnancies with known outcomes all with exposure in the first trimester. Miscarriage was reported in 4 of 23 (17%) pregnancies and major birth defects were reported in 0 of 19 (0%) live births. The rates of miscarriage and major birth defects were consistent with estimated background rates.Post-approval adverse reactions are reported voluntarily from a population of uncertain size. It is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.In prospectively reported spontaneous post-approval reports from 1986 to 2018, 105 women with known pregnancy outcomes were exposed to RECOMBIVAX HB during pregnancy following the last menstrual period. After excluding induced abortions (n=5), those with exposure in the third trimester (n=4), and those with an unknown exposure timing (n=6), there were 90 pregnancies with known outcomes with exposures in the first or second trimester. Miscarriage was reported for 7 of 90 (7.8%) pregnancies. Major birth defects were reported for 2 of 83 (2.4%) live born infants. The rates of miscarriage and major birth defects were consistent with estimated background rates. 8.2LactationRisk SummaryIt is not known whether RECOMBIVAX HB is excreted in human milk. Data are not available to assess the effects of RECOMBIVAX HB on the breastfed infant or on milk production/excretion.The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RECOMBIVAX HB and any potential adverse effects on the breastfed child from RECOMBIVAX HB or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to the disease prevented by the vaccine. 8.4 Pediatric UseSafety and effectiveness of RECOMBIVAX HB have been established in all pediatric age groups. Maternally transferred antibodies do not interfere with the active immune response to the vaccine. [See Adverse Reactions (6.1) and Clinical Studies (14.1 and 14.2).] The safety and effectiveness of RECOMBIVAX HB Dialysis Formulation in children have not been established. 8.5 Geriatric UseClinical studies of RECOMBIVAX HB used for licensure did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger subjects. However, in later studies it has been shown that a diminished antibody response can be expected in persons older than 60 years of age. 11 DESCRIPTION RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) is a sterile suspension of non-infectious subunit viral vaccine derived from HBsAg produced in yeast cells. A portion of the hepatitis B virus gene, coding for HBsAg, is cloned into yeast, and the vaccine for hepatitis B is produced from cultures of this recombinant yeast strain according to methods developed in the Research Laboratories of Merck Sharp & Dohme LLC, Rahway, NJ, USA.The antigen is harvested and purified from fermentation cultures of a recombinant strain of the yeast Saccharomyces cerevisiae containing the gene for the adw subtype of HBsAg. The fermentation process involves growth of Saccharomyces cerevisiae on a complex fermentation medium which consists of an extract of yeast, soy peptone, dextrose, amino acids and mineral salts. The HBsAg protein is released from the yeast cells by cell disruption and purified by a series of physical and chemical methods. The purified protein is treated in phosphate buffer with formaldehyde and then coprecipitated with alum (potassium aluminum sulfate) to form bulk vaccine adjuvanted with amorphous aluminum hydroxyphosphate sulfate. Each dose contains less than 1% yeast protein. The vaccine produced by the Merck Sharp & Dohme LLC, Rahway, NJ, USA method has been shown to be comparable to the plasma-derived vaccine in terms of animal potency (mouse, monkey, and chimpanzee) and protective efficacy (chimpanzee and human).The vaccine against hepatitis B, prepared from recombinant yeast cultures, is free of association with human blood or blood products.RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) is supplied in three formulations. [See How Supplied/Storage and Handling (16).]Pediatric/Adolescent Formulation (Without Preservative), 10 mcg/mL: each 0.5 mL dose contains 5 mcg of hepatitis B surface antigen.Adult Formulation (Without Preservative), 10 mcg/mL: each 1 mL dose contains 10 mcg of hepatitis B surface antigen.Dialysis Formulation (Without Preservative), 40 mcg/mL: each 1 mL dose contains 40 mcg of hepatitis B surface antigen.All formulations contain approximately 0.5 mg of aluminum (provided as amorphous aluminum hydroxyphosphate sulfate, previously referred to as aluminum hydroxide) per mL of vaccine. In each formulation, hepatitis B surface antigen is adsorbed onto approximately 0.5 mg of aluminum (provided as amorphous aluminum hydroxyphosphate sulfate) per mL of vaccine. The vaccine contains