HEPATITIS B, DIPHTHERIA, TETANUS, PERTUSSIS VACCINE

Description Diphtheria, Tetanus, Pertussis whole cell, Recombinant Hepatitis B and Hib Vaccine. Comvac5 is a sterile, whitish, cloudy, uniform suspension of Diphtheria toxoid, Tetanus toxoid, B pertussis whole Cell inactivated, Hepatitis B Surface Antigen and Hib PRP-TT Conjugate adsorbed on a mineral carrier Aluminum phosphate gel in isotonic saline solution. The contents, upon keeping, may settle down to deposit at bottom and disperse uniformly upon shaking. The Diphtheria and Tetanus components are the toxoids prepared from the toxins of cultures of Corynebacterium diphtheriae and Clostridium tetani by formalin inactivation using established technology. The Pertussis component is whole cell culture of Bordetella pertussis inactivated by using standard methods. The Hepatitis B Surface Antigen of the Hepatitis B virus is manufactured by recombinant DNA technology in genetically engineered yeast cells of Pichia pastoris which carry the gene that codes for the major surface antigen of the Hepatitis B virus. Hib PRP-TT Conjugate is purified Polyribosyl-Ribitol-Phosphate conjugated to Tetanus Toxoid.

Composition

Dose of 0.5 ml contains: Diphtheria Toxoid ..... 25 Lf (30 IU) Tetanus Toxoid ..... 7.5 Lf (60 IU) Inactivated w-B. pertussis ....20 OU (4 IU) HBsAg (rDNA) ....10 mcg Hib PRP-TT Conjugate ..... 10 mcg Aluminium Phosphate Gel as Aluminium (Al+++) ...0.3 mg Thiomersal (as Preservative) ....0.025 mg

Indications for Immunization Comvac5 is indicated for the primary immunization of infants and children, from the age of 6 weeks up to school going age of 6 years, against diseases of Diphtheria, Tetanus, Whooping Cough, Hepatitis caused by Hepatitis B virus and disease caused by H. influenzae Type b.

Contraindications Comvac5 should not be administered to infants or children with fever or other evidence of acute illness or infection. The presence of an evolving or changing neurological disorder is a contraindication to receipt of the vaccine. A personal or family history of central nervous system disease or convulsions is considered a contraindication to the use of this vaccine.

Elective immunization of individuals over six months of age should be deferred during an outbreak of poliomyelitis.

Comvac5 should not be administered to children over six years of age or to adults because of the danger of reactions to diphtheria toxoid or pertussis component.

The specific contraindications adopted by individual national health authorities should reflect a balance between the risk from the vaccine and the risk from the disease. Because the risk from the vaccine remains extremely low in comparison to the risk from the disease in many developing countries, authorities there may choose to offer immunization to children who are mildly to moderately ill or malnourished

Dosage Schedule

Primary immunization consists of 3 doses of vaccine of 0.5 mL, each covered with in the first 6 months of a child’ s age. The first dose shall be given at 6 weeks of a child’ s age. Each dose is administered at an interval of 4 weeks. As per the EPI Schedule adopted by the Government of India, a booster of DTwP vaccine is given at the age of 15 / 18 months; hence instead of DTwP vaccine, the Comvac5 vaccine is recommended at the age of 15-18 months. A second booster, as reinforcing dose

of the Comvac5 vaccine, can be given during school entry, at the age of 4-6 year’ s age.

Precautions The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be borne in mind.

Epinephrine Hydrochloride Solution (1:1000) should be available for immediate use, in case an anaphylactic or acute hypersensitivity reaction occurs.

A separate sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent the transmission of hepatitis or other infectious agents.

Adverse Reactions Mild local reactions consisting of erythema, pain, tenderness, swelling and induration at the site of injection are common, usually self-limited and subside without treatment.

A small lump may occasionally be observed at the site of injection that disappears after a few days.

Mild to moderate systemic reactions may occur following injection of the vaccine; these include one or more of the following symptoms like temperature elevation, drowsiness, fretfulness, anorexia, vomiting irritability and persistent crying. These symptoms occur during the first 24 hours of administration and may persist for one to two days.

If any of the following events occur after the administration of the vaccine, the decision to give subsequent doses of vaccine containing Pertussis whole cell component should be carefully considered:

Temperature of 400C (1040F) within 48 hours not attributed to any other known cause, shock, collapse, screaming, persistent crying for several hours, convulsions with or without accompanying fever, signs of encephalopathy, alteration of consciousness, focal neurologic signs, thrombocytopenia purpura etc.

Sudden-Infant-Death-Syndrome (SIDS) has been reported following administration of vaccine containing Diphtheria, Tetanus Toxoids and Pertussis vaccine. The significance of these reports is not clear.
The incidence of these reactions is unknown and may occur in extremely rare cases.

administration The vaccine should be administered by intramuscular injection in the anterolateral region of the thigh of infants and young children. The site of injection should be prepared with a suitable antiseptic. Do not inject subcutaneously or intravenously.
Each injection of the primary immunization series should be made at different sites.
If sterile disposable syringes and needles are not used, syringes and needles should be sterilized in an autoclave at 1210C for 30 minutes. Care should be taken to maintain sterility until use.
While using the multi-dose vial, care must be taken to use separate sterile syringes and needles for the administration of every dose. Used multi-dose vial that contains remaining vaccine must be stored at the recommended storage temperature and re-examined carefully prior to reuse. A multi-dose vial of Comvac5 vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all the following conditions are met.

The expiry date has not passed
The vaccines are stored under appropriate cold chain conditions
The vaccine vial septum has not been submerged in water
Aseptic technique has been used to withdraw all doses

Withdrawing the vaccine from a vial:

Shake the vial to disperse the contents thoroughly, immediately before each withdrawal of vaccine.

Remove the flip off seal; a small circular portion of rubber stopper is seen.

DO' NOT REMOVE THE RUBBER STOPPER FROM THE VIAL.

Apply a sterile piece of cotton moistened with a suitable antiseptic to the surface of the rubber stopper and allow to dry. Draw into the sterile syringe a volume of air equal to the amount of vaccine to be withdrawn from the vial. Pierce the centre of the rubber stopper with the sterile needle of the syringe, invert the vial, slowly inject into it the air contained in the syringe, and keeping the point of the needle immersed withdraw into the syringe the required amount of vaccine. Then hold the syringe plunger steady and withdraw the needle from the vial. Carefully insert the needle intramuscularly at the prepared injection site. In order to avoid intravenous injection, pull back the plunger of the syringe to make certain that no blood is withdrawn before injecting the desired dose. Handling of Pre-Filled Syringe with vaccine : Carefully remove PFS needle shield, ensure no air bubbles are present in the Syringe and inject intramuscularly to vaccinee.

Storage: 2°C to 8°C DO NOT FREEZE. DISCARD IF FROZEN

Keep out of reach of children.

Presentation Comvac5 is presented in USP type1 glass vial. Single dose vial 0.5 mL Multi dose vial (5 dose) 2.5 mL Multi dose vial (10 dose) 5.0 mL