

Patient Product Information

COMVAC 4-Hb[®]

(Fully Liquid Tetravalent Combination Vaccine)

Generic name: [Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (rDNA) Vaccine

Read this information with care before getting COMVAC 4-Hb[®]. You (the person getting COMVAC 4-Hb[®]) will need 3 doses of the vaccine. It is important to read this leaflet when you get each dose. This leaflet does not take the place of talking with your health care provider about COMVAC 4-Hb[®].

What is COMVAC 4-Hb[®] ?

COMVAC 4-Hb[®] is a tetravalent combinational vaccine. This vaccine helps to protect your child against diphtheria, tetanus, pertussis (whooping cough), and Hepatitis caused by Hepatitis-B virus.

It is given as a primary series vaccination in babies and as a booster vaccination in children who received this vaccine or a similar vaccine when they were younger.

What is COMVAC 4-Hb[®] used for ?

When an injection of COMVAC 4-Hb[®] is given, the body's defense mechanism will produce protection against these different diseases.

- Diphtheria is an infectious disease that usually first affects the throat. In the throat, the infection causes pain and swelling which can lead to suffocation. The bacteria that cause the disease also produce a toxin (poison) that can damage the heart, kidneys and nerves.
- Tetanus (often called lock jaw) is caused by the tetanus bacteria entering a deep wound. The bacteria produce a toxin (poison) that causes spasms of the muscles, leading to an inability to breathe and the possibility of suffocation.
- Pertussis (often called whooping cough) is an infection of the airways, that can occur at any age but mostly affects infants and young children. Increasingly severe coughing spells that can last for several weeks are a characteristic of the disease. Coughing spells may be followed by a whooping noise.
- Hepatitis-B is an infection of the liver resulting in irritation and swellings (inflammation) caused by hepatitis-b virus (HBV).

Important notes to keep in mind before using COMVAC 4-Hb® ?

It is important to tell your doctor, pharmacist or nurse if any of the points below apply to your child so that they can make sure that COMVAC 4-Hb® is suitable for your child.

COMVAC 4-Hb® 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.

COMVAC 4-Hb® 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.

Can COMVAC 4-Hb® be used with other medications ?

COMVAC 4-Hb® can be given at the same time as a measles-mumps-rubella vaccine. Your doctor or nurse will give the two injections at different injection sites and will use separate syringes for each injection.

Please tell your doctor, nurse or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

If there is anything you do not understand, ask your doctor, pharmacist or nurse to explain.

How is COMVAC 4-Hb® administered ?

The vaccination should be given by medical or healthcare professionals who are trained in the use of vaccines and who are equipped to deal with any allergic reactions from the injection.

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. Injection will not be subcutaneously or intravenously.

What is the dosage schedule for COMVAC 4-Hb® ?

Primary immunization consists of 3 doses of vaccine of 0.5 mL, each covered within 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 COMVAC 4-Hb® vaccine is recommended at the age of 15-18 months. A second booster, as reinforcing dose of the COMVAC 4-Hb® vaccine, can be given during school entry, at the age of 4-6 years age.

What are the possible side-effects upon immunizing with COMVAC 4-Hb® ?

Like all vaccines and medicines, COMVAC 4-Hb® can also cause side effects, although not everybody gets them.

- 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 40°C (104°F) 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 neurological 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. If any of these symptoms occur after leaving the place where your child received the injection,

you must consult a doctor **IMMEDIATELY**.

PROTECT YOURSELF AND ALL YOUR FAMILY MEMBERS TODAY.