

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Easyfive
Pentavalent Vaccine
For Intramuscular Injection only

For Active Immunization against Diphtheria, Tetanus, Whooping Cough, Haemophilus influenzae type b associated diseases and Hepatitis B



DESCRIPTION

Easyfive is a sterile and uniform suspension of diphtheria toxoid, tetanus toxoid, whole cell pertussis vaccine, Hepatitis B surface antigen and conjugated Haemophilus influenzae type b (CRM₁₉₇-Hib) vaccine adsorbed on aluminum phosphate and suspended in isotonic sodium chloride solution. Diphtheria and tetanus toxoids are obtained by detoxification of respective toxins by formalin. Pertussis vaccine is a suspension of heat-killed Bordetella pertussis of all the three major agglutinogens viz. 1, 2, and 3. Surface antigen of Hepatitis B virus is obtained from cultures of transformed yeast by insertion in its genome of the protein coding for the surface antigen (HbsAg) using recombinant DNA procedures. Haemophilus influenzae type b (CRM₁₉₇-Hib) vaccine is derived from highly purified capsular polysaccharide

COMPOSITION

Each dose (0.5ml) contains:

Diphtheria Toxoid.....	20 Lf
Tetanus Toxoid.....	7.5 Lf
Inactivated w-B. pertussis.....	12 OU (12000 x 10 ⁶ organisms)
HBsAg.....	10 mcg
H. influenzae type b oligosaccharides.....	10 mcg conjugated to CRM ₁₉₇ protein
Aluminum content [Al ³⁺].....	0.25 mg (As Aluminum Phosphate gel)
Thimerosal IP.....	0.025 mg
Water for injection IP.....	qs

INDICATIONS

Easyfive is indicated for primary active immunization against diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b [Hib] and hepatitis B (HB) in infants from 6 weeks onwards.

PHARMACOLOGICAL PROPERTIES

The Immunogenicity of **Easyfive** vaccine was evaluated in 6, 10,14 weeks schedule (3 doses given at 4 weekly intervals). The immune responses for the five components of the vaccine were as follows 1 month after the completion of 3-dose primary vaccination schedule.

Anti-diphtheria antibodies

100% of subjects developed protective antibody titers.

Anti-tetanus antibodies

100% of subjects developed protective antibody titers.

Anti-B pertussis antibodies

95.84% of subjects were considered to have responded to the vaccine (>4-fold rise in antibody titers).

100% of subjects developed protective antibody titers.

AntiHBs antibodies

100% of subjects developed protective antibody titers.

CONTRAINDICATIONS

The presence of any evolving or changing disorder affecting the central nervous system is a contraindication to administration of a pertussis containing vaccine such as **EasyFive** regardless of whether the suspected neurological disorder is associated with occurrence of seizure activity of any type.

Easyfive should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis, Hib or HB vaccines.

Easyfive is contra-indicated if the child has experienced an encephalopathy of unknown etiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances the vaccination course should be continued with DT, Hib and HB vaccines.

SPECIAL WARNINGS AND PRECAUTIONS

As with other vaccines, the administration of **Easyfive** should be postponed in subjects suffering from acute severe febrile illness.

If any of the following events occur in temporal relation to the administration of Easyfive the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered:

- Temperature of $\geq 40^{\circ}\text{C}$ within 48 hours, not due to another identifiable cause
- Collapse or shock-like state (hypotonic-hypo responsive episode) within 48 hours
- Persistent crying lasting ≥ 3 hours, occurring within 48 hours
- Convulsions with or without fever, occurring within 3 days.

There may be circumstances, such as a high incidence of pertussis, when the potential benefits outweigh possible risks.

A history of febrile convulsions, a family history of convulsions, a family history of SIDS (Sudden Infant Death Syndrome) or a family history of an adverse event following **Easyfive** vaccination do not constitute contra-indications.

HIV infection is not considered as a contra-indication for diphtheria, tetanus, pertussis, Hib and HB vaccination. The expected immunological response may not be obtained after vaccination of immunosuppressed patients, e.g., patients on immunosuppressive therapy.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after vaccination.

Easyfive should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Easyfive should under no circumstances be administered intravenously or subcutaneously.

INTERACTIONS

As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

Immunosuppressive therapies, including irradiations, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines. Short-term (< 2 weeks) corticosteroid therapy or intra-articular, bursal, or tendon injections with corticosteroids would not be immunosuppressive.

UNDESIRABLE EFFECTS

Mild reactions at the injection site, such as pain, local redness, warmth, oedema, induration with or without tenderness, as well as Urticaria and rash, are possible. Systemic reactions such as fever, restlessness, fretfulness, poor feeding, vomiting and diarrhea may appear in a few infants. Some data suggests that febrile reactions are more likely to occur in those who have experienced such responses after prior doses.

The frequency of local reactions and fever following this vaccination was not significantly higher with increasing number of doses, and other mild to moderate systemic reactions (e.g. fretfulness, vomiting) are infrequent.

Convulsions and thrombocytopenia have been reported very rarely with hepatitis B containing vaccines.

Fatigue, malaise, headache, arthralgias, myalgia, urticaria and anaphylaxis have been reported in rare cases.

DOSAGE AND ADMINISTRATION

For active immunization of infants, it is recommended that three intramuscular injections of Easyfive should be administered at an interval of four weeks between doses, starting at 6 weeks of age.

In countries where perinatal transmission of HB is common, the first dose of HB should be given as soon as possible after birth. In this case, the combination vaccine can be used to complete the primary series from 6 weeks of age.

A booster dose of DTwP and Hib can be given at the age of 15-18 months.

A reinforcing injection of DTwP should be administered at 5 years of age (i.e. at the time of school entry).

IAP (Indian Academy of Pediatrics) recommends that wherever combination vaccines are available, they can be substituted for monovalent formulations in the national Immunization schedule wherever indicated.

SHAKE WELL BEFORE USE

MODE OF ADMINISTRATION

Before filling the syringe, the vaccine vial should be well shaken to get a uniform suspension.

The vaccine should be administered by intramuscular injection. The anterolateral aspect of the thigh is the preferred injection site for infants.

The site of injection should be prepared with a suitable antiseptic. Do not inject subcutaneously or intravenously. Care should be taken to maintain sterility.

STORAGE INSTRUCTIONS

EasyFive should be stored at $5^{\circ}\text{C}\pm 3^{\circ}\text{C}$.

EasyFive should not be used after expiry date printed on the pack and vial do not freeze. Discard if the vaccine has been frozen.

PRESENTATION

One dose vial containing 0.5 ml of **Easyfive**.