**Easyfour**  
Tetravalent Vaccine  
For Intramuscular Injection only  
For Active Immunization against Diphtheria, Tetanus, Whooping Cough and Haemophilus influenzae type b associated diseases

**DESCRIPTION**

Easyfour is a sterile and uniform suspension of diphtheria toxoid, tetanus toxoid, whole cell pertussis vaccine and conjugated Haemophilus influenzae type b (CRM\textsubscript{197}-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. Haemophilus influenzae type b (CRM\textsubscript{197}-Hib) vaccine is derived from highly purified capsular polysaccharide isolated from Haemophilus influenzae type b coupled with CRM\textsubscript{197} protein, a non-toxic variant of diphtheria toxin.

**COMPOSITION**

Each dose (0.5ml) contains:

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

**INDICATIONS**

Easyfour is indicated for active immunization against diphtheria, tetanus, pertussis and *Haemophilus influenzae* type b [Hib] in infants from 6 weeks onwards. Three vaccine doses must be administered at intervals of at least 4 weeks. A booster vaccine dose should be administered at 15-18 months of age.

**PHARMACOLOGY**
Immunogenicity of Easyfour vaccine was evaluated in 6,10,14 weeks schedule (3 doses given at 4 weekly intervals). The immune responses for the four 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
83.5% of subjects were considered to have responded to the vaccine (>4-fold rise in antibody titers).

Anti-Hib antibodies
100% of subjects developed protective antibody titers.

CONTRAINDICATIONS

Easyfour 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, and pertussis or Hib vaccines.

Easyfour 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 and Hib vaccines.

SPECIAL WARNING AND PRECAUTIONS

If any of the following events occur in temporal relation to the administration of Easyfour the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered: • Temperature of 40°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 Easyfour vaccination does not constitute contra-indications.

HIV infection is not considered as a contra-indication for diphtheria, tetanus, pertussis and Hib 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.

Easyfour should under no circumstances be administered intravenously or
subcutaneously.

INTERACTIONS

**Easyfour** may be administered at the same time as other vaccines (like OPV, HBV) or human immunoglobulin; however the injections must be carried out using different syringes and into different parts of the body.

The immunological response of the vaccine may be reduced in patients undergoing therapy with corticosteroids or immunosuppressant

UNDESIRABLE EFFECTS

Local symptoms like redness, swelling and pain may be observed after the administration of the vaccine. A small lump may occasionally be noted in the site of the inoculation that disappears after a few days.

Systemic symptoms occasionally observed include the following: fever, drowsiness, irritability, persistent crying, loss of appetite, vomiting and diarrhoea. If the onset of these symptoms occurs within 48 hours after the administration of the vaccine they will, in the majority of cases, disappear spontaneously.

DOSAGE AND ADMINISTRATION

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

The customary age for the first dose of primary immunization is recommended to be 6 weeks of age. Specifically, Indian Academy of Paediatrics [IAP] recommends DTwP and Hib to be given at 6, 10 and 14 weeks of birth. Hence, the combination of **Easyfour** can be given at 6, 10 and 14 weeks.

A booster dose of DTwP and Hib is recommended at the age of 15-18 months.

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

The IAP 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 and deltoid for children.

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 AND STABILITY**

*EasyFour* should be stored at $5^\circ C \pm 3^\circ C$

*EasyFour* 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 *Easyfour*. 