

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and *Haemophilus influenzae* Type b Conjugate Vaccine (Adsorbed) IP

Easyfive-TT

Pentavalent Vaccine (DTwP-Hep B-Hib)

DESCRIPTION

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) & *Haemophilus Type b* Conjugate Vaccine (Adsorbed) IP (DTwP-Hep-B-Hib) (Easyfive-TT) 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 (PRP-TT) vaccine adsorbed on aluminium phosphate and suspended in isotonic sodium chloride solution. Thiomersal is added as a preservative. 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 gene coding for the surface antigen (HBsAg) using recombinant DNA procedures. *Haemophilus influenzae* type b (PRP-TT) vaccine is derived from highly purified capsular polysaccharide isolated from *Haemophilus influenzae* type b coupled with Tetanus toxoid.

The production process of Diphtheria, Tetanus, whole cell Pertussis, recombinant HBsAg and Hib vaccine complies with WHO recommendations.

The potency of the vaccine per single human dose is at least 30 IU for diphtheria, 60 IU for tetanus (determined in mice), 4IU for whole cell pertussis, ≥ 1.0 for Hepatitis B surface antigen (in vivo test) and 10 mcg conjugated *Haemophilus influenzae* type b (PRP-TT).

The final product has an appearance of a white or almost white material which sediments at the bottom of the container defining two phases: a clear supernatant essentially protein-free composed of physiological saline with the preservative substance dissolved, plus a aluminium phosphate gel with the antigen adsorbed on it. When shaken, a white or almost white suspension is formed, lasting for some minutes, which is the form in which the product is to be administered.

Composition

Single paediatric dose of 0.5 ml contains:

Diphtheria Toxoid	20 Lf (30 IU)
Tetanus Toxoid	7.5 Lf (60 IU)
Inactivated w-B. pertussis	12 OU (4 IU)
HBsAg	10 mcg
Hib (PRP-TT)	10 mcg
Aluminium (Al^{3+}) (As AlPO ₄ Gel)	0.25 mg
Thiomersal	0.025 mg
Physiological saline	qs.

ADMINISTRATION

The liquid vaccine vial should be shaken before use to homogenize the suspension. The vaccine should be injected intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of injection, or into the deltoid muscles of older children. An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended. It must not be injected into the skin as this may give rise to local reaction. One paediatric dose is 0.5 ml. A sterile syringe and sterile needle must be used for each injection.

IMMUNIZATION SCHEDULE

DTwP-HepB-Hib vaccine should **NOT** be used for the birth dose.

In countries where pertussis is of particular danger to young infants, the combination vaccine should be started as soon as possible with the first dose given as early as 6 weeks, and two subsequent doses given at 4-week intervals.

Easyfive-TT vaccine can be given safely and effectively at the same time as BCG, measles, polio (OPV or IPV), and yellow fever vaccines and vitamin A supplementation. If DTwP-HepB-Hib vaccine is given at the same time as other vaccines, it should be administered at a separate site. It should not be mixed in the vial or syringe with any other vaccine unless it is licensed for use as a combined product.

SIDE EFFECTS

The type and rate of severe adverse reactions do not differ significantly from the DTwP, HepB and Hib vaccine reactions described separately.

For DTwP, mild local or systemic reactions are common. Some temporary swelling, tenderness and redness at the site of injection together with fever occur in a large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Hypotonic-hyporesponsive episodes have been reported. Febrile convulsions have been reported at a rate of one per 12500 doses administered. Administration of acetaminophen at the time and 4-8 hours after immunization decreases the subsequent incidence of febrile reaction. The national childhood encephalopathy study in the United Kingdom showed a small increased risk of acute encephalopathy (primarily seizures) following

DTP immunization. However subsequent detailed reviews of all available studies by a number of groups, including the United States Institute of Medicine, the Advisory Committee on Immunization Practices, and the paediatric associations of Australia, Canada, the United Kingdom and the United States, concluded that the data did not demonstrate a causal relationship between DTwP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that these reactions have any permanent consequences for the children.

Hepatitis B vaccine is very well tolerated. In placebo-controlled studies, with the exception of local pain, reported events such as myalgia and transient fever have not been more frequent than in the placebo group. Reports of severe anaphylactic reactions are very rare. Available data do not indicate a causal association between hepatitis B vaccine and Guillain-Barre syndrome, or demyelinating disorders including multiple sclerosis, nor is there any epidemiological data to support a causal association between hepatitis B vaccination and chronic fatigue syndrome, arthritis, autoimmune disorders, asthma, sudden infant death syndrome, or diabetes.

Hib vaccine is very well tolerated. Localized reactions may occur within 24 hours of vaccination, when recipients may experience pain and tenderness at the injection site. These reactions are generally mild and transient. In most cases, they spontaneously resolve within two to three days and further medical attention is not required. Mild systemic reactions, including fever, rarely occur following administration of Hib vaccine. More serious reactions are very rare; a causal relationship between more serious reactions and the vaccine has not been established.

In case you experience any undesirable effect following intake of this medication please feel free to contact us at any of the following contact details: e-mail id: pyg@panaceabiotec.com; Fax no.: +91-11-41679069; M.No.+91-9650138282.

CONTRAINDICATIONS

Known hypersensitivity to any component of the vaccine or a severe reaction to a previous dose of the combination vaccine or any of its constituents is an absolute contraindication to subsequent doses of the combination vaccine or the specific vaccine known to have provoked an adverse reaction. There are few contraindications to the first dose of DTwP, fits or abnormal cerebral signs in the newborn period or other serious neurological abnormality are contraindications to the pertussis component. In this case, the vaccines should not be given as a combination vaccine but DT should be given instead of DTwP and HepB and Hib vaccines given separately. The vaccine will not harm individuals currently or previously infected with the hepatitis B virus.

Immune deficiency

Individuals infected with the human immuno-deficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with combined vaccine according to standard schedules.

STORAGE

The combination vaccine must be stored and transported at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

The DTwP-Hep B-Hib vaccine **MUST NOT BE FROZEN**.

PRESENTATION

Single dose vial containing 0.5 ml vaccine.

Figure of the Vaccine Vial Monitor (VVM)

The vaccine vial monitor ...

-  ✓ Inner square is lighter than outer circle.
If the expiry date has not been passed, USE the vaccine.
-  ✓ At a later time, inner square still lighter than outer circle.
If the expiry date has not been passed, USE the vaccine.
-  ✗ Discard point:
Inner square matches colour of outer circle.
DO NOT use the vaccine.
-  ✗ Beyond the discard point:
Inner square darker than outer circle.
DO NOT use the vaccine.

Vaccine Vial Monitors (VVMs) supplied by TEMPTIME Corporation, U.S.A are put on all Easyfive-TT vaccine vials. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. "Focus on the central square". If the colour of this square is lighter than the colour of the circle, the vaccine can be used. If the colour of the central square is same as that of the circle or darker than the circle, the vaccine vial should be discarded.

Manufactured by:

Panacea Biotec Ltd.

Malpur, Baddi,

Distt. Solan (H.P.) - 173 205, India.