Size : 95 x 245 mm

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

Rx

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

[Easyfive-TT®]

Fully Liquid Pentavalent Vaccine

DESCRIPTION

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) & *Haemophilus influenzae* 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 gel 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), 4 IU for whole cell pertussis, 10 mcg for Hepatitis B surface antigen and 10 mcg for 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 aluminum 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

One 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
H. influenzae type b (PRP) conjugated to Tetanus Toxoid	10 mcg
Aluminium content (Al^{3+}) (As Aluminium Phosphate Gel)	0.25 mg
Thiomersal	0.025 mg
Physiological saline	q.s.

*Bulk source : PT. BioFarma, Indonesia

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

Easyfive-TT® 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 Measles, polio vaccines (OPV or IPV) and vitamin A supplementation.

If Easyfive- TT® 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

Side Effects 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.

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.

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.

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: pvg@panaceabiotec.com; Fax no.: +91-11-41578085; M.No.+91-9650138282.

The following Precautions should be taken care of:
The administration of Easyfive- TT® should be postponed in subjects suffering from acute severe febrile illness.

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

- Temperature of >40.0 °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.

Easyfive-TT® should be administered with caution to subjects with a bleeding disorder.
Medical treatment should always be available in case of anaphylactic reactions. The patient should remain under medical supervision for 30 minutes after vaccination. Easyfive- TT® should under no circumstances be administered intravenously or subcutaneously.

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 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.

SHELF LIFE

Shelf life is 36 months when stored at 5 ± 3°C.

STORAGE

The combination vaccine must be stored and transported at 5°C ± 3°C. The DTwP-Hep B-Hib vaccine MUST NOT BE FROZEN.

Multi-dose vials of Easyfive- TT® 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 of the following conditions are met:

- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum (rubber stopper) has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

PRESENTATION

Single dose pre-filled syringe containing 0.5 ml vaccine supplied along with 25G needle of 1˝.

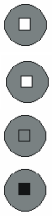
Single Paediatric dose vial containing 0.5 ml vaccine#.

Multidose vial containing 5 ml (10 Paediatric doses) vaccine#.

(# Vial Presentations are provided with vaccine vial monitor (VVM))

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 Flip of seal of all Easyfive- TT® vaccine vials. 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 of darker than the circle, the vaccine vial should be discarded.

WITHDRAWING THE VACCINE FROM A VIAL

Shake the vial to disperse the contents thoroughly immediately before each withdrawal of vaccine.
Remove the flip of seal and 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.

PREPARATION FOR INJECTION (PFS)

Remove the prefilled syringe from the blister pack. Holding the syringe barrel, remove the Plastic rigid cap (PRTC) from the tip of syringe. The PRTC design makes the tip cap easy to open and promote aseptic technique by reducing risk of syringe tip contamination during cap removal.
Attach the needle to the Luer Lok syringe.
In the unusual event of the piston rod becoming loose off, screw it clockwise in to the plunger in order to secure it.
The peel-off label on the barrel of the prefilled syringe is to be pasted on the vaccinee's vaccination card for future reference.
Each prefilled syringe should be used only once.

Manufactured by:
Panacea Biotec Ltd.
Malpur, Baddi,
Distt. Solan (H.P.) - 173 205, India.

Last updated on April 2018

Panacea Biotec
Innovation in support of life

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