

# Packaging Insert of Easyfour (UNICEF Supply)

Size : 245 x 95 mm



Panacea Biotec

## Diphtheria, Tetanus, Pertussis (Whole Cell) and Haemophilus Type b Conjugate Vaccine (Adsorbed) IP

(DTwP-Hib)

# Easyfour™

### DESCRIPTION

Diphtheria, Tetanus, Pertussis (Whole Cell), Haemophilus Type b Conjugate Vaccine (Adsorbed) IP (DTP-Hib) (Easyfour) is a sterile and uniform suspension of Diphtheria toxoid, Tetanus toxoid, whole cell Pertussis vaccine and conjugated *Haemophilus influenzae* type b (CRM<sub>197</sub>-Hib) 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. *Haemophilus influenzae* type b (CRM<sub>197</sub>-Hib) vaccine is derived from highly purified capsular polysaccharide isolated from *Haemophilus influenzae* type b coupled with CRM<sub>197</sub> protein, a non-toxic variant of Diphtheria toxin.

The production process of Diphtheria, Tetanus, whole cell Pertussis and CRM<sub>197</sub>-Hib vaccine complies with WHO recommendations.

The potency of the vaccine per single human dose is at least 30 IU for diphtheria, 40 IU for tetanus (determined in guinea pig) or 60 IU for tetanus (determined in mice), 4IU for

### COMPOSITION

	Paediatric Dose
Each paediatric dose contains:	0.5 ml
Diphtheria Toxoid	20Lf (30IU)
Tetanus Toxoid	7.5Lf
	(40 IU in guinea pigs and 60 IU in mice)
Inactivated w- <i>B.pertussis</i>	12 OU (4IU)
Hib-CRM <sub>197</sub>	10 mcg
Aluminium (Al <sup>3+</sup> ) (As AlPO <sub>4</sub> Gel)	0.25 mg
Thiomersal	0.025 mg
Physiological saline	qs

### ADMINISTRATION

Easyfour vaccine vial should be shaken 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 dose is 0.5ml. A sterile syringe and sterile needle should be used for each injection.

### IMMUNIZATION SCHEDULE

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.

Easyfour can be given safely and effectively at the same time as BCG, measles, polio (OPV and IPV), hepatitis B, and yellow fever vaccines and vitamin A supplementation.

### SIDE EFFECTS

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

For DTP, 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 reactions.

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.

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.

### CONTRAINDICATIONS

Easyfour vaccine should not be given to individuals who had an anaphylactic reaction to a previous dose or to any constituent of the vaccine.

### 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 vaccine should be stored and transported between 5°C ± 3°C.





The **DTwP-Hib 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 Easyfour 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 of darker than the circle, the vaccine vial should be discarded.

Manufactured by:

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