

Packaging Insert of Ecovac4(UNICEF Supply)

Size : 245 x 95 mm



Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) Vaccine (Adsorbed) IP

(DTwP-Hep B)

Ecovac4™

DESCRIPTION

Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) Vaccine (Adsorbed) IP (DTwP-Hep B) (Ecovac4) is a sterile, opaque, uniform suspension of Diphtheria toxoid, Tetanus toxoid, whole cell Pertussis vaccine and Hepatitis B surface antigen 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 the Hepatitis B virus (HBV) is obtained from cultures of a transformed yeast by the insertion in its genome of the gene coding for the surface antigen (HBsAg) using recombinant DNA procedures.

The production process of Diphtheria, Tetanus, whole cell Pertussis and recombinant HBsAg 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 whole cell pertussis and ≥ 1.0 for Hepatitis B surface antigen (in vivo test).

COMPOSITION

	Paediatric Dose
Each paediatric dose contains:	0.5 ml
Diphtheria Toxoid	20 Lf (30 IU)
Tetanus Toxoid	7.5 Lf
	(40 IU in guinea pigs and 60 IU in mice)
Inactivated w-B.pertussis	12 OU (4IU)
r-Hepatitis B surface Antigen	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 0.5ml.

A sterile syringe and sterile needle must be used for each injection.

IMMUNIZATION SCHEDULE

DTwP-HepB 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.

The DTwP-HepB 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 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 DTP and HepB 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 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.

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. Report 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.

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 Hep B 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 vaccine must be stored and transported between 5°C ± 3°C.





The **DTwP-Hep B 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 Ecovac4 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:
Panacea Biotec Ltd.
A-241, Okhla Indl. Area-1,
New Delhi - 110 020, India.