

Información acerca del producto - Information concerning the product

☒ **DTP-HB<sup>®</sup> VACCINE**

☒ **VACCIN DTP-HB<sup>®</sup>**

☒ **VACUNA DTP-HB<sup>®</sup>**

☒ **VACINA DTP-HB<sup>®</sup>**

☒ **DTP-HB<sup>®</sup> вакцина**



**BIO FARMA**

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Vaccine is a liquid containing purified diphtheria and tetanus toxoids, inactivated whooping cough (pertussis) organisms, and highly purified, non-infectious particles of hepatitis B surface antigen (HBsAg). The HBsAg is produced by DNA recombinant technology in yeast (*Hansenulla polymorpha*) cells. The vaccine is adsorbed onto 3 mg/ml aluminum phosphate. Thimerosal 0.1 mg/ml is used as a preservative. The potency of the vaccine per single human dose is at least 4 IU for pertussis, 30 IU for diphtheria and for tetanus 60 IU (determined in mice) and upper fiducial limit relative potency for Hepatitis B of not less than 1.0 (in vivo test). The vaccine is used for the prevention against diphtheria, tetanus, pertussis and hepatitis B simultaneously.

COMPOSITION	Paediatric Dose
Volume	0.5 ml
Purified Diphtheria toxoid	20 Lf
Purified Tetanus toxoid	7.5 Lf
Inactivated B. Pertussis	12 OU
HBsAg	10 mcg
Aluminum phosphate	1.5 mg
Thimerosal	0.05 mg

#### 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 deltoid muscles for 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 pediatric dose is 0.5 ml. A sterile syringe and sterile needle must be used for each injection.

#### IMMUNIZATION SCHEDULE

The vaccine should NOT be used for the birth dose of Hepatitis B.

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 vaccine can be given safely and effectively at the same time as BCG, measles and polio vaccines (OPV or IPV), Hib and Yellow Fever vaccine and vitamin A supplementation. If DTP-HB 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 adverse reactions do not differ significantly from the DTP and Hep B 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 of 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 DTP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that hypotonic-hyporesponsive episode and febrile convulsions 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 event 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 - Barré 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 DTP - 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 DTP 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 +2°C and +8°C. **The DTP-HB  MUST NOT BE FROZEN.**

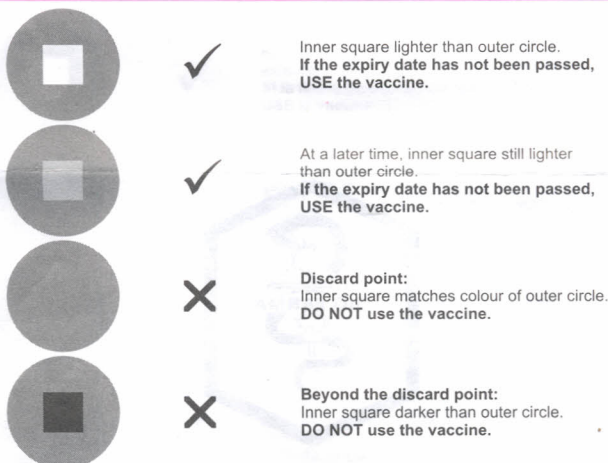
Multi-dose vials of vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization session for up to a maximum of 4 weeks, provided that all of following conditions are met (as described in the WHO policy statement : *The use of opened multi-dose vials in subsequent immunization sessions*. WHO/V&B/00.09) :


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

#### PRESENTATION

The vaccine comes in vials of 2.5 ml (5 doses) and 5ml (10 doses)

### FIG. THE VACCINE VIAL MONITOR



Vaccine Vial Monitors (VVMs) supplied by TempTime, are part of the label on **DTP-HB ** vaccine. 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. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the outer circle or of a darker colour as than the outer circle, then the vial should be discarded.



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