

## SUMMARY OF PRODUCT CHARACTERISTICS

## NAME OF THE MEDICINAL PRODUCT

Bio Td Vaccine

## NAME AND ADDRESS OF MANUFACTURER

PT. Bio Farma (Persero)

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Indonesia

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## QUALITATIVE AND QUANTITATIVE COMPOSITION

## Composition:

Each dose (0.5 ml) of vaccine contains:

Purified tetanus toxoid	7.5 Lf
Purified diphtheria toxoid	2 Lf
Aluminium Phosphate	1.5 mg
Thimerosal	0.05 mg

## PHARMACEUTICAL FORM

Suspension for injection

## CLINICAL PARTICULARS

**Therapeutic indications:**

Booster immunization against tetanus and diphtheria of individuals aged 7 years onwards

**Posology and method of administration:**

The vaccine should be injected intramuscularly in the upper arm. A single 0.5 ml dose of the vaccine is recommended. The use of Bio Td to replace other Diphtheria and Tetanus containing vaccines should be in accordance with official recommendation due to the low dose of diphtheria toxoid in this vaccine. The use of vaccine for primary immunization and in pregnancy has not been evaluated. It may be given at the same time as measles, polio (OPV and IPV), hepatitis B, yellow fever vaccines and vitamin A supplementation.

**Contraindication**

A second or subsequent dose of Bio Td should not be given to an individual who suffer a severe reaction to the previous dose

**Immune deficiency**

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic should be immunized with Bio Td according to standard schedules

**Special warning and precaution for use:**

- The vaccine should be shaken before use to homogenous the suspension
- Before use, the information at vaccine vial monitor (VVM) must be followed.

**Note:**

The ACIP (Advisory Committee on Immunization Practices) has published recommendation for use of Tetanus and Diphtheria Toxoids Adsorbed, for adult use in pregnant women. Bio Td vaccine may be used as a primary immunization for persons contraindicated for DTP vaccine, from 7 years of age. According to ACIP (Advisory Committee on Immunization Practices), they should receive two doses of 0.5 ml of Bio Td with reduced dose of diphtheria for adults at an interval of at least four-eight weeks. A third dose is recommended at least 6 months after the second dose.

**Interaction with other medicinal products and other forms of interaction**

There is no drug interaction.

**Pregnancy and lactation:**

The use of vaccine in pregnancy has not been evaluated.

**Effects on ability to drive and use machines:**

Not applicable

**Undesirable effects:**

Some transitional local pain (20-30%) and fever (4.7%) were reported during the clinical trial.

**Overdose:**

Not applicable.



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## PHARMACEUTICAL PARTICULARS

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**Excipients:**

Aluminium phosphate  
Thimerosal

**Incompatibilities:**

Not applicable

**Shelf-life:**

The shelf-life of Bio Td Vaccine is 3 years from the date of manufacture.  
The expiry date is shown on the label.

**Special precautions for storage:**

Bio Td Vaccine should be protected from light and store between 2°C and 8°C, do not freeze.

**Nature and content of container:**

The vaccine comes in vials 0.5 and 5 ml (1 and 10 doses)

**Instructions for use, handing and disposal:**

- Shake well before use.
- A sterile needle and a sterile syringe should be used for each injection.
- If anticipated to have been contaminated, vaccine has to be immediately destroyed.

**MODEL INSERT  
ADSORBED DT VACCINE FOR CHILDREN**

**DESCRIPTION**

The vaccine contains purified diphtheria and tetanus toxoids. The toxoids are adsorbed onto .....(specify). .....(specify) is used as a preservative. The potency of vaccine components per single human dose is at least 30 IU (International Units) of potency for diphtheria toxoid and at least 40 IU of potency for tetanus toxoid.

**COMPOSITION**

**Paediatric Dose**

Volume	0.5 ml
Diphtheria toxoid	xx Lf/ml ( .....IU/ml )
Tetanus toxoid	xx Lf/ml ( .....IU/ml )
Nature of Aluminium salt and quantity as AL <sup>+++</sup>	XX mg/ml
Nature and amount of preservatives	XX mg/ml

**ADMINISTRATION**

The vaccine vial should be shaken before use to homogenize the suspension. The vaccine should be injected intramuscularly. A sterile syringe and a sterile needle should be used for each injection. DT vaccine is recommended for children below 7 years of age. For persons 7 years and older, a special adsorbed vaccine for adults, Td, is recommended.

**IMMUNIZATION SCHEDULE**

Three intramuscular injections of 0.5 ml at least four weeks apart provide primary immunization for children. DT may be given at the same time as, Measles, , Polio vaccines (OPV and IPV), Hepatitis B, Yellow Fever vaccine and Vitamin A supplementation.

**SIDE EFFECTS**

Some temporary tenderness and redness at the site of the injection and occasional fever may occur.

**CONTRAINDICATIONS**

A second or subsequent dose of DT should not be given to a child who suffered a severe reaction to the previous dose.

***Immune deficiency***

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with DT vaccine according to standard schedules.

**STORAGE**

DT should be stored and transported between +2°C and +8°C. IT MUST NOT BE FROZEN.

Once opened, multi-dose vials should be kept between +2°C and +8°C. **Multi-dose vials of DT 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 (as described in the *WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. WHO/V&B/00.09*):

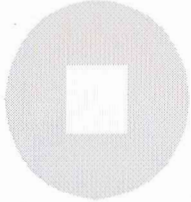
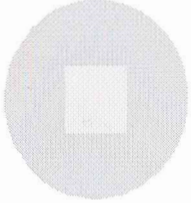

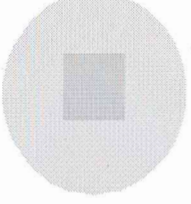
- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point. (see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

### PRESENTATION

The vaccine comes in vials of .... (specify) doses.

Fig. The Vaccine Vial Monitor

## The vaccine vial monitor...

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

Vaccine Vial Monitors (VVMs) are part of the label on .....(specify vaccine) supplied through .....(specify supplier or manufacturer). 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

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ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.