SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

Final Bulk of Adsorbed Td Vaccine

NAME AND ADDRESS OF MANUFACTURER

PT. Bio Farma (Persero)
Jalan Pasteur 28
Bandung 40161
Indonesia
Telephone: 62 22 2033755
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Website: WWW.biofarma.co.id

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

Sterile Suspension

CLINICAL PARTICULARS

Therapeutic indications:
Booster immunization against tetanus and diphtheria of individuals aged 7 years of age older against tetanus and diphtheria.
As final bulk/ready to fill is intended for further manufacturing step for filling and it becomes to Adsorbed Td Vaccine
**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 Adsorbed Td vaccine 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 Absorbed 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 Adsorbed Td vaccine 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.

**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**

**Excipients:**
- Aluminium phosphate
- Thimerosal

**Incompatibilities:**
- Aluminium phosphate
Shelflife:
The shelf-life of Final Bulk of Adsorbed Td Vaccine is 1 year from the date of manufacture. The expiry date is shown on the label.

Special precautions for storage:
Vaccine should be stored and transported between 2°C and 8°C, do not freeze.

Nature and content of container:
5, 9, 12, 15 and 20 liter of polypropylene bottle.

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.