SUMMARY OF PRODUCT CHARACTERISTICS

Adsorbed Td Vaccine

Product Name	**: Adsorbed Td Vaccine**
Pharmaceutical Form	**: Suspension for injection**
Strength	**: 1 and 10 doses**
Presentation	**: Box of 10 ampoules @ 0.5 mL (1 ds)**
	Box of 10 vials @ 5 mL (10 ds)

PT BIO FARMA (PERSERO)
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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name:

Adsorbed Td Vaccine

1.2 Strength:

1 and 10 ds.

1.3 Pharmaceutical dosage form:

Suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The vaccine contains purified tetanus and diphtheria toxoids, with a reduced dose of the diphtheria component. One dose of 0.5 mL has a potency of less than 30 IU of diphtheria toxoid, and not less than 40 IU of Tetanus toxoid. The toxoids are adsorbed onto 3 mg/mL aluminum phosphate. Thimerosal 0.1 mg/mL is used as a preservative.

Composition:

Each dose (0.5 ml) of vaccine contains:

Purified diphtheria toxoid	2 Lf
Purified tetanus toxoid	7.5 Lf
Al^{3+} as aluminum phosphate	1.5 mg
Thimerosal	0.05 mg

3. PHARMACEUTICAL FORM

Whitish suspension, homogenous after shaking.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Active immunization of adults and children 7 years of age and older against diphtheria and tetanus.

4.2 Posology and method of administration:

The vaccine vials/ampoules should be shaken to homogenize the suspension. The vaccine should be injected intramuscularly in the upper arm. A sterile syringe and a sterile needle should be used for each injection.

A single 0.5 mL dose of the vaccine is recommended. The use of Td vaccine to replace other Diphtheria and Tetanus containing vaccines should be in accordance with the 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 vaccine, Polio vaccine (OPV and IPV), Hepatitis B vaccine, Yellow fever vaccine and vitamin A supplementation.
Note :
The ACIP (Advisory Committee on Immunization Practices) has published recommendation for the use of Tetanus and Diphtheria Toxoids Adsorbed for adult use in pregnant women. Td vaccine may be used as a primary immunization for person contraindicated to DTP vaccine, from 7 years of age. According to ACIP, they should receive two doses of 0.5 ml of adsorbed Td for adult at an interval at least 4-8 weeks. A third dose is recommended at least 6 months after the second dose.
According to WHO insert model, “Td vaccine may be used as a primary immunization for persons from 7 years of age. They should receive two dose of 0.5 ml of adsorbed Td with reduced dose of diphtheria for adults at an interval of at least 4 weeks. A third dose is recommended at least 6 months after the second dose. After a primary immunization course of either DTP or Td, adsorbed Td for adults may be used as a booster at intervals of approximately 10 years, but with a minimum of at least one year between doses. It can safely replace monovalent tetanus toxoid (TT) vaccine, including during pregnancy.”

4.3 Contraindications:

A second or subsequent dose of Td 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 combined vaccine according to standard schedules.

4.4 Special warnings and precautions for use:

- The vial/ampoule should be shaken before use to homogenize the suspension.
- The vaccine should be injected intramuscularly
- A sterile syringe and sterile needle should be used for each injection
- Before use, information on Vaccine Vial Monitor (VVM) must be followed (only applied for adsorbed Td 10 ds).
- Keep the container in the outer carton in order to protect from light

4.5 Interaction with other medicinal products and other forms of interaction:

No interaction studies have been performed.

4.6 Pregnancy and lactation:

The use of adsorbed Td vaccine in pregnancy has not been evaluated. However The ACIP (Advisory Committee on Immunization Practices) has published recommendation for use of Tetanus and Diphtheria Toxoids Adsorbed for adult in pregnant women.
It is stated as well in the WHO insert model, “It can safely replace monovalent tetanus toxoid (TT) vaccine, including during pregnancy.”

4.7 Effects on ability to drive and use machines:

There is no evidence that adsorbed Td vaccine effects on ability to drive and use machines.

4.8 Undesirable effects:

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

4.9 Overdose:

Since registered, we never received report about adsorbed Td Vaccine overdose. No data may support this event.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties:

- Pharmacotherapeutic group : Vaccines
- ATC code : J07AM51
- Mechanism of action (if known) : Stimulates the body to produce antibody against tetanus and diphtheria.
- Pharmacodynamic effects : No study has been performed.
- Clinical efficacy and safety : Refer to sections 2.5, 2.7 and module 5 in the Dossier of Adsorbed Td Vaccine.

5.2 Pharmacokinetic Properties:

No related study has been performed.

5.3 Preclinical safety data:

No related study has been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

Al^{3+} as aluminum phosphate
Thimerosal

6.2 Incompatibilities:

No related study has been performed.

6.3 Shelf life:

The shelf life of Adsorbed Td Vaccine 1 and 10 ds are 3 years, stored at +2°C ~ +8°C. The expiry date is shown on the label.

6.4 Special precautions for storage:

Adsorbed Td vaccine should be protected from light, 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.

6.5 Nature and contents of container:

Adsorbed Td vaccines are available in following presentations:
Box @ 10 ampoules @ 0.5 mL (1 ds)
Box @ 10 vials @ 5 mL (10 ds)

6.6 Instructions for use, handling and disposal:

- The vaccine should be shaken to homogenize the suspension
- The vaccine should be injected intramuscularly in the upper arm
- A sterile needle and a sterile syringe should be used for each injection
- Multi-dose vials of Pentabio (DTP-HB-Hib) from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunisation session for up to maximum of 4 weeks, provided that all of following condition are met (*as described in the WHO policy statement : Multi-dose Vial Policy (MDVP)WHO/IVB/14.07*):
  - ✓ The vaccine is currently prequalified by WHO;
  - ✓ The vaccine is approved for use up to 28 days after opening the vial, as determined by WHO;
  - ✓ The expiry date has not passed;
  - ✓ The vaccine vial has been and will continue to be stored at WHO-or manufacturer-recommended temperatures; furthermore, the vaccine vial monitor (VVM), if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBERS

- Adsorbed Td 1 ds (box @10 ampoules @ 0.5 mL) : GKL0802901643B2
- Adsorbed Td 10 ds (box @10 vials @ 5 mL) : GKL0802901643B1

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization:

- Adsorbed Td 1 ds (box @ 10 ampoules @ 0.5 mL) : 25 November 2014
- Adsorbed Td 10 ds (box @ 10 vials @ 5 mL) : 16 December 2008

Date of renewal of the authorization:

- Adsorbed Td 1 ds (box @ 10 ampoules @ 0.5 mL) : 21 July 2024
- Adsorbed Td 10 ds (box@10 vials@ 5mL) : 05 September 2023

10. DATE OF REVISION OF THE TEXT

August 2022