## 1. NAME OF THE MEDICINAL PRODUCT

**Name:** Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents I.P

**Trade Name:** BE Td®

**Presentation:**

Single dose vial of 0.5 mL

Ten dose vial of 5 mL

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Each dose of 0.5 mL Contains:**

| | |
|---|---|
| Diphtheria Toxoid | : ≥ 2 IU |
| Tetanus Toxoid | : ≥ 5 Lf to ≤ 25 Lf or ≥ 20 IU |
| Adsorbed on Aluminium Phosphate (as $AlPO_4$) | : ≥ 1.5 mg |
| Preservative: Thiomersal | : 0.01% w/v |

For full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Suspension for Intramuscular Injection.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

BE Td® is indicated for active immunization of children 7 years of age or older, adolescents and adults against tetanus and diphtheria.

In order to prevent adverse reactions to the protein of diphtheria toxoid in this group, the quantity of the toxoid has been markedly reduced.

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.



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Shameerpet
R.R. Dist (T.S.)
INDIA.

## 4.2. Posology and method of administration

**Posology**

The primary schedule of two injections of 0.5 mL at least four weeks apart followed by a third injection 6 to 12 months after the second dose. The vaccine should also be given as a single booster immunization every 10 years.

**Method of administration**

The vaccine should be injected intramuscularly. The preferred site for injection is deltoid muscle of the upper arm. Care should be taken not to inject into the blood vessel or the skin. The vaccine should be well shaken before use. Product which has been exposed to freezing should not be used.

The vaccine should be visually inspected for any foreign particulate matter and /or variation of physical aspect prior to administration. In event of either being observed discard the vaccine.

## 4.3. Contraindications

The vaccine should not be given to persons who showed a severe reaction to a previous dose of Diphtheria and/or Tetanus vaccine. A history of systemic allergic or neurologic reactions following a previous dose of Td is an absolute contraindication for further use.

Immunization should be deferred during the course of an acute illness. Vaccination of persons with severe, febrile illness should generally be deferred until these persons have recovered. However, the Presence of minor illnesses such as mild upper respiratory infections with or without fever should not preclude vaccination.

## 4.4. Special warnings and precautions for use

The possibility of allergic reactions in individuals sensitive to the component of the vaccine should be kept in mind. Epinephrine injection (1:1000) must be immediately available should an acute anaphylactic reaction occur to any component of the vaccine. All known precautions should be taken to prevent adverse reactions. This includes the review of the patient's history with respect to possible sensitivity and any previous adverse reactions to the vaccine or similar vaccine, previous immunization history and current health status.

A separate sterile needle and syringe should be used for each individual to prevent transmission of infectious agents. As with the use of all vaccines, the vaccine should remain under observation for not less than 30 minutes for any possibility of occurrence of immediate or early allergic reactions.

### 4.5. Interaction with other medicinal products and other forms of interaction

As with other intramuscular injections, use with caution in patients on anticoagulant therapy. Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids may reduce the immune response to vaccines.

### 4.6. Pregnancy and lactation

The effect of BE Td®, on pregnancy and lactation has not been assessed.

### 4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

### 4.8. Undesirable effects

Reactions are generally mild and confined to the site of injection. Some inflammation may occur together with systemic effects including transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare.

### 4.9. Overdose

This section is not applicable for this product.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

This section is not applicable for this product.

### 5.2. Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

### 5.3. Preclinical safety data

During the course of 14 day acute systemic toxicity study in mice and rabbits injected with combination vaccine containing D and T antigens, no abnormalities were observed in the treatment as well as control group. None of the animals died during the study period and there were no observation of sign of toxicity related to general behavior, nervous system and respiratory systems in both the groups. The food consumption data also revealed no statistical significance in between the groups. The organ weights also show no changes. Histopathological examination of the prime organs also revealed any notable changes.

The 90 day chronic systemic toxicity study in separate groups of mice and rabbits injected with multiple doses of combination vaccine containing D and T antigens were also carried out. The general behavior pattern showed no sign of toxicity in all four treatment groups. Statistically insignificant differences were observed between the control and treatment groups in both mice and rabbits in respective body weight changes which can be inferred as uniform growth during the long study period.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Aluminium Phosphate (AlPO4)

Thiomersal (Preservative)

### 6.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### 6.3. Shelf life

36 months from the date of manufacture.

### 6.4. Special precautions for storage

The vaccine should be stored at a temperature between 2°C to 8°C and should be protected from light. Do not freeze.

### 6.5. Nature and contents of container

The vaccine is filled in USP Type I glass vials closed bromobutyl rubber stoppers and sealed with aluminium flip-off seals.

The vaccine is offered in following presentations.

Single dose - 0.5 mL

Ten dose - 5 mL

### 6.6. Special precautions for disposal

Discard if the vaccine has been frozen as per the approved procedures.

## 7. MARKETING AUTHORISATION HOLDER

**M/s. Biological E. Limited.**

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## 8. MARKETING AUTHORISATION NUMBER(S)

MF-142/2013

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

12/07/2013

*For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only*

Date: 09/2016

BIOLOGICAL E. LIMITED Shameerpet R.R. Dist (T.S.) INDIA.