

**Registration No. 2C 3/60 (B)**

**Importer / Manufacturer: Biogenetech Co. Ltd. / Biological E. Limited**

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICAL PRODUCT**

**BE Td®**

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each dose of 0.5 mL contains:

Diphtheria Toxoid	2 Lf ( $\geq 2$ IU)
Tetanus Toxoid	8.8 Lf ( $\geq 20$ IU)
Adsorbed on Aluminium Phosphate (AlPO <sub>4</sub> )	$\geq 1.5$ mg
Preservative: Thiomersal BP	0.01% w/v

### **3. PHARMACEUTICAL FORM**

BE Td® (Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen (s) Content)) is prepared by combining purified diphtheria toxoid and purified tetanus toxoid. The antigens are adsorbed onto Aluminium Phosphate as adjuvant. Thiomersal is added as preservative. The vaccine meets the requirements of WHO and BP.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

BE Td® is indicated for active immunization of children 7 years of age or older, 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.

It may be given at the same time as measles, polio (OPV & IPV), hepatitis B, yellow fever vaccines and vitamin A supplementation.

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.

This vaccine is not to be used for the treatment of tetanus or diphtheria infection.

#### **4.2 Posology and method of administration**

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

Children who remain in completely immunized after seventh birthday should be counted as having prior exposure to tetanus and diphtheria toxoid.

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

#### **4.3 Contraindication**

The vaccine should not be given to persons who showed a severe reaction to a previous dose of Diphtheria and 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.

### ***IMMUNE DEFICIENCY***

Individuals infected with human immune deficiency virus (HIV) both asymptomatic and symptomatic, should be immunised with Td Vaccine according to standard schedules.

#### **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 vaccines, previous immunization history and current health status.

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

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.

#### **4.5 Interaction with other medical products and forms of interaction**

N/A

#### **4.6 Pregnancy and lactation**

N/A

#### **4.7 Effects on the ability to drive and use machines**

N/A

#### **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**

N/A

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

N/A

### **5.2 Pharmacokinetic properties**

N/A

### **5.3 Preclinical safety data**

N/A

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Adsorbed on Aluminium Phosphate (AlPO<sub>4</sub>), Thiomersal BP

### **6.2 Incompatibilities**

N/A

### **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.

Once opened, multi dose vials of BE Td® 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:

- 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.
- Vaccine Vial Monitor (VVM) has not reached the discard point.

### **6.5 Nature and contents of container**

1 dose vial of 0.5 mL

10 doses vial of 5 mL

### **6.6 Special precautions for disposal and other handling**

N/A

## **7. MARKETING AUTHORISATION HOLDER**

Biogenetech Co., Ltd.

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## **8. MARKETING AUTHORISATION NUMBER(S)**

2C 3/60 (B)

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

September 7, 2017

## **10. DATE OF REVISION OF THE TEXT**

July 5, 2018