

WHO website لا طبياً  
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C.C.I 18/11

## BETd Pack Insert for Export

Black

80 x 190 mm

### DIPHTHERIA AND TETANUS VACCINE (ADSORBED, REDUCED ANTIGEN(S) CONTENT BETd®)

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.

#### 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 Td vaccine 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.

#### SHELF LIFE:

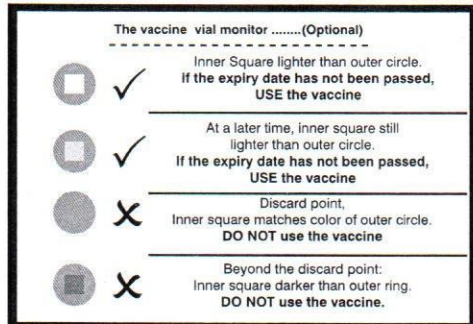
36 months from the date of manufacture

#### PRESENTATION:

1 dose vial of 0.5 mL

10 dose vial of 5 mL

Presentation available with or without vaccine vial monitor.



Vaccine Vial Monitor (VVM) is part of the label. The colour dot 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 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.

#### DESCRIPTION:

BETd® (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.

#### COMPOSITION:

Each dose of 0.5 mL contains:

Diphtheria Toxoid

Tetanus Toxoid

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

Preservative: Thiomersal BP

0.01% w/v

#### INDICATIONS:

BETd® 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.

No safety and immunogenicity data are available on the concomitant administration of this vaccine with other licensed vaccines.

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.

#### APPLICATION AND DOSAGE:

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.

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

#### METHOD OF INOCULATION:

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. 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.

#### ADVERSE REACTIONS:

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.

#### PRECAUTIONS:

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.

#### CONTRAINDICATIONS AND WARNINGS:

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.

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



Manufactured by: **Biological E. Limited**

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