Registration No. 1C 15008/62 (NB)

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

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

BETT®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 mL contains:

Tetanus Toxoid	≥ 40 IU
Adsorbed on Aluminium phosphate (AlPO4)	≥ 1.5 mg
Preservative: Thiomersal BP	0.01% w/v

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tetanus prophylaxis: Adsorbed Tetanus vaccine is indicated for active immunization against tetanus in adults, children and in infants 6 weeks of age or older. Monovalent Adsorbed Tetanus vaccine should not be used in children less than 7 years of age. In children less than 7 years of age, the use of diphtheria, tetanus and pertussis (DTwP) vaccine combination is recommended unless pertussis vaccine is contraindicated. If pertussis is contraindicated then the use of diphtheria and tetanus toxoids (DT) is recommended.

Post exposure prophylaxis of tetanus: Tetanus infection may not confer immunity; therefore initiation or completion of active immunization is indicated at the time of recovery from this infection.

Neonatal tetanus prevention: If vaccination is required, tetanus toxoid can be used during pregnancy. Teratogenic effects have not been reported with tetanus toxoid in humans. Waiting until the second trimester to administer tetanus vaccine is a reasonable precaution for minimizing any concern regarding the theoretical possibility of adverse reactions.

Tetanus Prophylaxis in Wound Management: Tetanus toxoid can also be used prophylactically for wound management in persons 7 years of age and older; tetanus and diphtheria toxoid (Td) is preferred, to maintain adequate levels of diphtheria immunity.

4.2 Posology and method of administration

Posology

Immunization schedule: The primary immunizing course for unimmunised individuals 7 years of age or older consists of two doses or 0.5 mL each 4 to 8 weeks apart followed by a third (reinforcing) dose of 0.5 mL, 6 to 12 months after the second dose. The reinforcing dose is an integral part of primary immunizing course. Individuals who have not completed primary immunization against tetanus, or whose immunization history is unknown or uncertain, should be immunized with a tetanus toxoid containing-product.

TT may be given at the same time as BCG, measles, rubella, mumps, polio (OPV and IPV), hepatitis B, Haemophilus influenzae type b, and yellow fever vaccines and vitamin A supplementation.

For neonatal tetanus prevention: Antenatal immunization is recommended for the prevention of neonatal tetanus in the previously unimmunized mother. A previously unimmunized pregnant woman who may deliver her child under non hygienic circumstances and/or surroundings should receive two doses of a tetanus toxoid-containing preparation before delivery (4 to 8 weeks apart), preferably during the last 2 trimesters. Incompletely immunized pregnant women should complete the 3 dose series. Those immunized more than 10 years previously should have a booster dose.

Table-Tetanus toxoid immunization schedule for pregnant women and women of child bearing age

Recommended Schedule	**Dose 1**	**Dose 2**	**Dose 3**	**Dose 4**	**Dose 5**
Pregnant women with no previous immunization (or unreliable immunization)	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**
	As early as possible in first pregnancy	At least 4 weeks later	At least 6 months later	At least 1 year later	At least 1 year later
Pregnant women with 3 childhood DTP doses	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**
	As early as possible in first pregnancy	At least 4 weeks later	At least 1 year later, or in next pregnancy		
Pregnant women with 4 childhood DTP doses	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**
	As early as possible in first pregnancy	At least 1 year later, or in next pregnancy			
Supplementary immunization activities in high risk areas (women of childbearing age)	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**	**TT or Td**
	During round 1	During round 2, at least 4 weeks after round 1	During round 3, at least 6 months after round 2	At least 1 year later, (in next pregnancy)	At least 1 year later, (in next pregnancy

Source: WHO EPI 2006

In tetanus prophylaxis in wound management: The need for active immunization with a tetanus toxoid-containing preparation, with or without passive immunization with TIG (Human) depends on both the condition of the wound and the patient's vaccination history. Tetanus toxoid vaccine in conjunction with tetanus immune globulin is recommended for prophylactic contaminated wound management in unimmunized, uncertain, or incomplete immunization status patients.

A thorough attempt must be made to determine whether a patient has completed primary immunization. Individuals who have completed primary immunization against tetanus, and who sustain wounds which are minor and uncontaminated, should receive a booster dose of a tetanus toxoid-containing preparation only if they have not received tetanus toxoid within the preceding 10 years.

For tetanus prone wounds (e.g. wounds contaminated with dirt, faeces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns, and frostbite), a booster is appropriate if the patient has not received a tetanus toxoid-containing preparation within the preceding 5 years. If a booster dose is given sooner than 10 years as part of wound management the next routine booster should not be given for 10 years thereafter.

Human Immunodeficiency Virus (HIV) infected persons

HIV-infected persons, both asymptomatic and symptomatic, should be immunized with Adsorbed Tetanus vaccine according to standard schedules.

Method of administration

The vaccine should be administered by intramuscular injection.

The vaccine ampoule should be shaken before use to homogenize the suspension. A sterile needle and a sterile syringe should be used for each injection.

4.3 Contraindication

Hypersensitivity to any component of the vaccine, including thiomersal, a mercury derivative, is a contraindication.

Do not use the vaccine in person with report of anaphylactic reaction after receiving vaccine with TT antigen.

The occurrence of any type of neurological symptoms or signs, following administration of this product is a contraindication to further use. Immunization should be deferred during the course of any febrile illness or acute infection. A minor afebrile illness such as a mild upper respiratory infection is not usually reason to defer immunization.

The attending physician should consider risk/benefit ratio at all times. Routine immunization should be deferred during an outbreak of poliomyelitis provided the patient has not sustained an injury that increases the risk of tetanus.

4.4 Special warnings and precautions for use

Special warnings

The occurrence of a neurologic or severe hypersensitivity reaction following a previous dose is a contraindication to further use of this product. The administration of booster doses more frequently than recommended may be associated with increased incidence and severity of reactions. Persons who experience Arthus-type hypersensitivity reactions or temperature greater than 39□C after a previous dose of tetanus toxoid usually have very high serum tetanus antitoxin levels and should not be given even emergency doses of tetanus toxoid more frequently than every 10 years, even if they have a wound that is neither clean nor minor.

Adsorbed Tetanus Vaccine should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration.

Patients with impaired immune responsiveness may have a reduced antibody response to active immunization procedures.

Special care should be taken to prevent injection into blood vessel.

Precautions

1. Prior to administration of any dose of vaccine, the parent, guardian, or adult patient should be asked about the recent health status and immunization history of the patient to be immunized in order to determine the existence of any contraindication to immunization.
2. When the patient returns for the next dose in a series, the parent, guardian, or adult patient should be questioned concerning occurrence of any symptom and/or sign of an adverse reaction after the previous dose.
3. Before the injection of any biological the physician should take all precautions known for prevention of allergic or any other side reactions. This should include: a review of the patient's history regarding possible sensitivity, the ready availability of epinephrine 1:1000 and other appropriate agents used for control of immediate allergic reactions.
4. A separate sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent transmission of hepatitis or other infectious agents from one person to another.
5. Shake vigorously before withdrawing each dose to re-suspend the contents.

4.5 Interaction with other medical products and forms of interaction

It is current practice in pediatric vaccination to co-administer different vaccines during the same session with injectable vaccines being administered at separate injection sites.

Tetanus Toxoid Vaccine can be administered simultaneously at separate sites or in any temporal relationship with other pediatric vaccines if this fits conveniently in the immunization scheme.

4.6 Pregnancy and lactation

Fertility

Not studied.

Pregnancy

Animal reproductive studies have not been conducted with this product. There is no evidence that Adsorbed Tetanus Vaccine is teratogenic. Adsorbed Tetanus Vaccine should be given to inadequately immunize pregnant women because it affords protection against neonatal tetanus. Waiting until the second trimester is a reasonable precaution to minimize any theoretical concern.

Lactation

Not applicable, as Tetanus Toxoid Vaccine is already given during pregnancy.

4.7 Effects on the ability to drive and use machines

Adsorbed Tetanus Vaccine is not reported to have any influence on the ability to drive and use machines.

4.8 Undesirable effects

Local reactions, such as pain, erythema, induration, and tenderness, are common after the administration of Tetanus Toxoid. Such local reactions are usually self limited and require no therapy. Nodule, sterile abscess formation, or subcutaneous atrophy may occur at the site of injection. Systemic reactions, such as fever, chills, myalgias, and headaches, also may occur. Arthus type hypersensitivity reactions, or high fever, may occur in persons who have very high serum antitoxin antibodies due to frequent injections of toxoid. Neurological complications such as convulsions, encephalopathy, and various mono and polyneuropathies, including guillain-barre syndrome, have been reported following administration of preparations containing tetanus antigen. Urticaria, erythema multiforme or other rash, arthralgias, and more rarely, a severe anaphylactic reaction (i.e., urticaria with swelling of the mouth, difficulty in breathing, hypotension, or shock) have been reported following administration of preparations containing tetanus antigen.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tetanus toxoid, ATC code: J07AM01

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium phosphate, thiomersal, sodium hydroxide, hydrochloric acid, water for injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Three years from the date of manufacture.

6.4 Special precautions for storage

Do not freeze. Store between 2□C to 8□C. Discard if the vaccine has been frozen.

6.5 Nature and contents of container

1 dose ampoule of 0.5 mL

6.6 Special precautions for disposal and other handling

The vaccine is available as a suspension. Upon storage, a white deposit and clear supernatant may be observed. The vaccine should be shaken well in order to obtain a homogenous turbid white suspension and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above being observed, discard the vaccine.

7. MARKETING AUTHORISATION HOLDER

Biogenetech Co., Ltd.
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8. MARKETING AUTHORISATION NUMBER(S)

1C 15008/62 (NB)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 January 2019

10. DATE OF REVISION OF THE TEXT

January 2020