1. NAME OF THE MEDICINAL PRODUCT

Name: Tetanus Vaccine (Adsorbed) I.P.

Trade Name: BETT

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:

Tetanus Toxoid	: ≥ 5 Lf to ≤ 25 Lf
Adsorbed on Aluminium Phosphate ($AlPO_4$)	: ≥ 1.5 mg
Preservative: Thiomersal I.P.	: 0.01 % w/v

For full list of excipients, refer section 6.1

3. PHARMACEUTICAL FORM

Tetanus Vaccine (Adsorbed) IP, Suspension for intramuscular injection. White turbid suspension in which mineral carrier tends to settle on keeping.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Tetanus Vaccine (Adsorbed) IP is indicated for prevention of Tetanus Infections.

4.2. Posology and method of administration

Posology

The primary immunizing course of Tetanus Vaccine (Adsorbed) IP for unimmunized individuals 7 years of age or older consists of two doses of 0.5mL each, 4 to 8 weeks apart followed by a third (reinforcing) dose of 0.5mL, 6 to 12 months after the second dose. The reinforcing dose is an integral part of the primary immunizing course.

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A booster dose of 0.5 mL of Tetanus Toxoid is given 10 years after completion of primary immunization and every 10 years thereafter. If a dose is given sooner than 10 years, as a part of wound management the next booster dose is not needed for 10 years thereafter.

Method of administration

The vaccine should be injected intramuscularly, preferably into deltoid muscle region of the upper arm, with care to avoid major peripheral nerve trunks. After insertion of the needle, aspirate to help avoid inadvertent injection into a blood vessel. Shake vigorously before withdrawing each dose to re-suspend the contents of the vial or syringe.

4.3. Contraindications

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

Warnings

The occurrence of a neurologic or severe hypersensitivity reaction following 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 (103° F) 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.

Tetanus vaccine (Adsorbed) IP 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.

Precautions

1. Prior to administration of any dose of vaccine, the parent, guardian or adult or patient should be asked about the recent health status and immunization history to be immunized in order to determine the existence of any contraindication to immunization.
2. When the vaccine returns for the next dose in a series, the parent, guardian or adult or patient should be questioned concerning occurrence of any symptom and/or sign of an adverse reaction after the previous dose.
3. Before the administration of any biological product 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 to prevent transmission of hepatitis or other infectious agents from one person to another.
5. Shake vigorously before withdrawing each dose to resuspend the contents of the vial.

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

Not established

4.6. Pregnancy and lactation

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

4.7. Effects on ability to drive and use machines

Not established.

4.8. Undesirable effects

Local reactions, such as erythema, induration and tenderness are common after the administration of Tetanus Toxoid. 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

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 T antigen, 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 T antigen 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 (as AlPO4)

Thiomersal I.P.

6.2. Incompatibilities

In the absence of compatibility studies, Tetanus Vaccine 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

Do Not Freeze. Store between +2°C to +8°C. Discard if the vaccine has been frozen.

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

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8. MARKETING AUTHORISATION NUMBER(S)

MF-196/2013

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

04/09/2013

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

Date: 09/2016

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