1. NAME OF THE MEDICINAL PRODUCT AND STRENGTH

1.1 Brand Name : TTvax Injection
1.2 Generic Name: Tetanus Toxoid (Adsorbed)
1.3 Strength : Tetanus Toxoid (Adsorbed on Aluminium Phosphate Gel) ≥ 40 IU per dose

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Each dose of 0.5 ml contains:

Tetanus toxoid	:	≥40 IU
Aluminium ($Al^{+3)}$ (As Aluminium Phosphate Gel)	:	≤1.25 mg
Thiomersal as Preservative	:	0.01% w/v
Sodium Chloride saline	:	q.s. to 0.5 ml

3. PHARMACEUTICAL FORM

3.1 **TTvax** Injection (Tetanus Toxoid Adsorbed BP) is a sterile suspension of tetanus toxoid for intramuscular injection. White turbid suspension in which minerals carrier tends to settle on keeping.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tetanus vaccine (Adsorbed) BP is indicated for prevention of Tetanus Infections.

4.2 Posology and Method of Administration

4.2.1 Posology

4.2.1.1 Primary vaccination:

The primary immunizing course of Tetanus Vaccine BP for unimmunized individuals 7 years of age or older consists of two doses of 0.5 ml each, at least 4 weeks apart followed by a third dose of 0.5 ml, 6 to 12 months after the second dose. To maintain a high level of immunity further 0.5 ml booster doses are recommended at every feasible interval (for adults 5 to 10 years).

4.2.1.2 Vaccination of Injured Person

For those subjects who have proof of either completing their course of primary immunizations containing tetanus toxoid or receiving a booster shot within the previous 5 years no additional dose of tetanus toxoid is recommended. If more than 5 years have elapsed and infection with tetanus because of injury or other cause is suspected, 0.5 ml of the TTvax Injection should be given immediately. Where the immunization history is inadequate 1500 IU (3000 old AU) tetanus antiserum and 0.5 ml TTvax Injection should be injected with separate syringes, to different body sites. (If available, 250 units of tetanus immune globulin (human origin) can be substituted for the tetanus antiserum). A second 0.5 ml dose of TTvax is recommended after 2 weeks and third dose after a further 1 month.

4.2.1.3 Protection of the Newborn against Tetanus

For prevention of neonatal tetanus, TTvax is recommended for the Immunization of the women of childbearing age and especially pregnant women. TTvax may be safely administered during pregnancy and should be given to the mother at first

contact or as early possible in pregnancy. A five dose schedule is recommended for previously unimmunized women of childbearing age: after the basic course of immunization with three doses, two additional booster should be given, at least one year after the previous dose or during the subsequent pregnancy.

4.2.2 **Pediatric Population**

4.2.2.1 Should not be used in children below 7 years of age because of safety and efficacy.

4.2.2.2 The safety and efficacy of TTvax injection in children aged below 7 years has not been established.

4.2.3 **Method of Administration**

4.2.3.1 TTvax Injection should be injected intramuscularly, preferably into deltoid muscle region of the upper arm, with care to avoid major peripheral nerve trunks. After insertion of needle, aspirate to help avoid inadvertent injection into a blood vessel. Shake well before withdrawing each dose to re-suspend the contents of the vials.

4.3 Contraindications

4.3.1 Hypersensitivity to any component of the vaccine, including thiomersal a mercury derivative, is a contraindication. **TTvax** injection is contraindicated in patients with previous hypersensitivity to any tetanus containing vaccine. Immunization should be deferred during the course of any febrile illness or acute infection. A minor febrile illness such as a mild upper respiratory infection should not preclude immunization.

4.4 Special warnings and precaution for use

4.4.1 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 the reactions. Persons who experience Arthus-type hypersensitivity reactions or temperature greater than 39ºC (103º F) after a previous dose of tetanus antitoxin levels and should not be given even emergency doses of tetanus toxoid more frequently than 10 years, even if they have a wound that is neither clean nor minor. Tetanus vaccine (adsorbed) 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.

4.4.2 Precautions

4.4.2.1 Prior to administration of any dose of vaccine, the parent, guardian or adults or patients should be asked about the recent health status and immunization history of the one to be immunized in order to determine the existence of any contraindication to immunization.

4.4.2.2 When the vaccinee 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.

4.4.2.3 Before the administration of any biological product the physician should take all precautions known for prevention of allergic or any other side reaction. 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 immediate allergic reactions.

4.4.2.4 Shake well before withdrawing each dose to re-suspend the contents of the vials.

4.5 Interaction with Other Medicinal Products and Other Forms of Interactions

4.5.1 **TTvax** injection can be safely and effectively given simultaneously with other vaccine BCG, Measles, Polio vaccines (OPV and IPV), Hepatitis-B, Haemophilus influenzae type B, Yellow fever vaccines and Varicella vaccine.

4.6 Fertility,Pregnancy and Lactation

4.6.1 Animal reproductive studies have not been conducted with this product. There is no evidence that tetanus vaccine BP is teratogenic.Tetanus vaccine (adsorbed) BP 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

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

4.8 Undesirable Effects

4.8.1 **Local reaction:** Erythema, induration and tenderness are common after the administration of **TTvax** injection. Such local reactions are usually self-limited and require no therapy.

4.8.2 **Systemic reaction:** Fever, chills, myalgia and headache are reported less commonly.

4.9 Overdose

No case of overdose has been reported.

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 vaccine.

5.3 Preclinical safety Data

5.3.1 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 no 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

6.1.1 Aluminium phosphate gel as adjuvant
6.1.2 Thiomersal as preservative
6.1.3 Sodium chloride as physiological saline

6.2 Incompatibilities

6.2.1 In the absence of compatibility studies, TTvax Injection must not be mixed with other medicinal products.

6.3 Shelf Life

2 years or material expiry whichever is less.

6.4 Special precautions for storage

6.4.1 Keep out of the reach and sight of children.
6.4.2 Store and transport at 2 ºC to 8 ºC.
6.4.3 Do not freeze. Discard vaccine if frozen.
6.4.4 Protect from light.
6.4.5 Shake well before use.

6.5 Nature and contents of container and special equipment for use, administration or implantation

6.5.1 TTvax Injection is filled in USP Type I glass vials closed with bromobutyl rubber stoppers and sealed with aluminium flip-off seals. The vaccine is offered as 0.5 ml single dose along with 2 ml sterile disposable syringe in a plastic tray.

6.6 Special precautions for disposal and other handling

6.6.1 Discard if the vaccine has been frozen as per approved procedures.
6.6.2 The vaccine should be inspected visually in order to detect any appearance of precipitate or discoloring of the content prior to administration. If these conditions exist, the product should not be administered.
6.6.3 Before use, the vial should be well shaken.
6.6.4 Once the vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.
6.6.5 Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER NAME AND ADDRESS

Head Office Address:

Popular Pharmaceuticals Ltd.
Sheltech Panthokunjo, 17 Shukrabad, West Panthopath, Dhaka - 1207, Bangladesh
Email: info@popularbd.com
Phone: +880-2-9101730-2, +880-2-9102850-3
Fax: +880-2-9134054, +880-2-9134096
Mobile: +880-1833332352-55

Factory Address:

Popular Pharmaceuticals Ltd.
164, Tongi Industrial Area, Monnunagar,
Gazipur – 1710, Bangladesh
Email: info@popularbd.com
Phone: +880-2-9812971-5
Fax: +880-2-9812976

8. MARKETING AUTHORIZATION NUMBER

MA No.: 336 – 476 – 069

9. DATE OF FIRST AUTHORIZATION/RENEWEL OF AUTHIRIZATION

Date of First Authorization : 15.03.2011
Date of Latest Renewal : 10.05.2022

10. DATE OF REVISION OF THE TEXT

08.08.2023