

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

BIO-TT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) contains :

Purified Tetanus Toxoid	10	Lf
Aluminium Phosphate (as adsorban)	1.5	mg
Thimerosal (as preservative)	0.05	mg

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TT is use in the prevention of neonatal tetanus by immunizing women of childbearing age, and also in the prevention of tetanus.

4.2 Posology and method of administration

Immunization schedule

TT immunization for the prevention of tetanus / neonatal tetanus consist of two primary doses of 0.5 ml given intramuscularly at least four weeks apart followed by the third dose 6 months later. To maintain the immunity of women against tetanus through the child bearing period, five doses are recommended. The fourth dose should be given at least one year after the third dose, and the fifth dose should be given at least one year after the fourth dose. TT immunization can be administered safely during pregnancy even during the first trimester.

Administration

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

4.3 Contraindication

A severe reactions to a previous dose of TT, hypersensitive to any component of the vaccine, immunization should be deferred during the cause any febrile illness or acute infection.

4.4 Special warnings and precautions for use

A minor febrile illness such as mild upper respiratory infection is not usually reason to defer immunization.

4.5 Interaction with other medical products and forms of interaction

N/A

4.6 Pregnancy and lactation

TT immunization can be administered safely during pregnancy even during the first trimester.

4.7 Effects on the ability to drive and use machines

N/A

4.8 Undesirable effects

Rare and mild. Some temporary tenderness and redness at the site of the injection and occasional fever. It is safe to give during pregnancy. Allergic acute reactions, dyspnea, urticaria, angioneurotic oedema, anaphylactic and acute reaction may occurred.

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

Aluminium Phosphate, Thimerosal

6.2 Incompatibilities

N/A

6.3 Shelf life

3 years

6.4 Special precautions for storage

TT should be stored and transported between 2 – 8 °C. DO NOT FREEZE

6.5 Nature and contents of container

Ampoules 0.5 ml (single dose)

Box of 10 ampoules

6.6 Special precautions for disposal and other handling

N/A

7. MARKETING AUTHORISATION HOLDER

BioNet-Asia Co.,Ltd.
Bangkok, THAILAND

8. MARKETING AUTHORISATION NUMBER(S)

1C 1/62 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

June 11, 2004

10. DATE OF REVISION OF THE TEXT

April 5, 2013