SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

TT VACCINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The vaccine contains purified tetanus toxoids. The toxoid is adsorbed onto 3 mg/ml aluminum phosphate. Thimerosal 0.1 mg/ml is used as a preservative. One dose of 0.5 ml has a potency of at least 40 IU.

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TT is used 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 consists of two primary doses of 0.5 ml given intramuscularly at least four weeks apart followed by the third dose at least 6 months later. To maintain the immunity of women against tetanus through the child-bearing period, a total of five doses are recommended. A fourth dose should be given at least one year after the third dose and a fifth dose at least one year after the fourth dose. TT immunization can be administered safely during pregnancy even during the first trimester. In previously non-immunized women, two doses of TT are recommended in pregnancy, at least 4 weeks apart, the second dose should be given at least two weeks before childbirth, in order to prevent maternal and neonatal tetanus.

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

Administration

The vaccine vial should be shaken before use to homogenize the suspension. It should be injected intramuscularly.

A sterile needle and a sterile syringe should be used for each injection.

Once opened, multi-dose vials should be kept between +2 ^{0}C and +8 ^{0}C. **Multi-dose vials of TT from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization session for up to a maximum of 4 weeks**, provided that all of the following conditions are met. (as described in the WHO policy statement : The use of opened multi-dose vials in subsequent immunization session WHO/V&B/00.09):

- 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;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point

4.3 Contraindication

A severe reaction to a previous dose of TT. There is no contraindication about persons infected with human immunodeficiency virus (HIV) whether asymptomatic or symptomatic.

4.4 Special warnings and precautions for use

N/A

4.5 Interaction with other medical products and forms of interaction

N/A

4.6 Pregnancy and lactation

It is safe to give during pregnancy.

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 be given during pregnancy.

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 vaccine should be stored and transported between +2 ˚C and +8 ˚C. IT MUST NOT BE FROZEN.

6.5 Nature and contents of container
The vaccine comes in vials of 10 doses.

6.6 Special precautions for disposal and other handling
N/A

7. MARKETING AUTHORISATION HOLDER
BioNet-Asai Co., Ltd.
Bangkok, THAILAND

8. MARKETING AUTHORISATION NUMBER(S)
1C 2/62 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
November 1, 2003

10. DATE OF REVISION OF THE TEXT
May 25, 2011