SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
ADSORBED DT VACCINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
The vaccine contains purified diphtheria and tetanus toxoids. The toxoids are adsorbed onto 3 mg/ml aluminum phosphate. Thimerosal 0.1 mg/ml is used as a preservative. The potency of vaccine components per single human dose is at least 40 IU (International Units) of potency for Diphtheria toxoid and at least 15 IU of potency for tetanus toxoid.

3. PHARMACEUTICAL FORM
Suspension for intramuscular or deep subcutaneous injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Prophylactic immunization against Diphtheria anf Tetanus

4.2 Posology and method of administration
Immunization schedule

Recommended for use in childhood immunization instead of DTP when contraindications to pertussis components exist. Three intramuscular injection of 0.5 ml at least four weeks apart provide primary immunization for children, DT may be given at the same as BCG, measles, rubella, mumps, polio vaccines (OPV and IPV), hepatitis B, Hib and yellow fever vaccines

Administration

The vaccine vial should be shaken before use to homogenize the suspension. The vaccine should be injected intramuscularly or deep subcutaneously. A sterile syringe and a sterile needle should be used for each injection. DT vaccine is recommended for children below 6 years of age. For person 6 years and older a special adsorbed vaccine for adults, Td is recommended.

Once opened, multi-dose vials should be kept between 2 $^{\circ}$C and 8 $^{\circ}$C. Opened vials may be used in subsequent immunization sessions provided that the following conditions are met. (WHO/EPI/LHIS/95. Revision July 1st 1999, or later).

a. The expiry date has not passed
b. The vaccine have been stored under appropriate cold chain conditions (2 $^{\circ}$C - 8 $^{\circ}$C)
c. Opened vials of vaccine, which are not supplied with VVM and which have been taken out of the health centre for immunization activities (e.g. outreach or supplementary immunization activities) are discarded at the end of the day.

An opened vials must be discarded immediately if any of the following conditions applies:

a. Sterile procedure have not been fully observed
b. There is even a suspicion that the opened vial has been contaminated, or
c. There is visible evidence of contamination, such as change in appearance or floating particles.

4.3 Contraindication

A second or subsequent dose of DT should not be given to a child who suffered a severe reactions to the previous dose. Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with DT vaccine according to standard schedules. .

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

N/A

4.7 Effects on the ability to drive and use machines

N/A

4.8 Undesirable effects

Some temporary tenderness and redness at the site of the injection and occasional fever:

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

2 years

6.4 Special precautions for storage

Adsorbed DT Vaccine should be stored and transported between 2 °C - 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-Asia Co.,Ltd.
Bangkok, THAILAND

8. MARKETING AUTHORISATION NUMBER(S)

2C /62 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 30, 2004

10. DATE OF REVISION OF THE TEXT

December 3, 2010