

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

DTP VACCINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The vaccine contains purified diphtheria and tetanus toxoids and inactivated whooping cough organisms. The toxoids are adsorbed onto 1.5 mg/ml aluminum phosphate. Thimerosal 0.05 mg/ml is used as a preservative. The potency of the vaccine per single human dose is 12 OU for pertussis, 20 Lf for diphtheria and for tetanus 7.5 Lf.

3. PHARMACEUTICAL FORM

Suspension for intramuscular or deep subcutaneous injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylactic immunization against Diphtheria, Tetanus and Pertussis

4.2 Posology and method of administration

Immunization schedule

In countries where pertussis is of particular danger to young infants, DTP immunization should be started as soon as possible with the first dose given as early as 6 weeks, and two subsequent doses given at 4 weeks intervals.

DTP vaccine can be given safely and effectively at the same time as BCG, measles and polio vaccines (OPV and IPV), hepatitis B, Hib and Yellow Fever Vaccines.

Administration

The vaccine vial should be shaken to homogenize the suspension. The vaccine should be injected intramuscularly or deep subcutaneously. The anterolateral aspect of the upper thigh is the preferred site of injection. (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended). It must not be injected into the skin as this may give rise to local reaction. One dose is 0.5 ml. A sterile needle and sterile syringe should be used for each injection.

Once opened, multi-dose vials should be kept between 2 °C and 8 °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 °C - 8 °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

There are few contraindications to the first dose of DTP. Fits or abnormal cerebral signs in the newborn period or the other serious neurological abnormality are contraindications to the pertussis component. DT should be given instead. A second or subsequent dose of DTP should not be given to a child who has suffered a severe reactions to the previous dose. The pertussis component should be omitted, and only DT given for the remainder of the course. Individual infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with DTP 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 swelling, tenderness and redness at the site of injection together with fever occur in large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Very rare neurological complications allegedly due to the pertussis component, have been observed but are rare in comparison to those observed in the course of disease.

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

DTP 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 1/62 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 30, 2004

10. DATE OF REVISION OF THE TEXT

December 3, 2010