**SUMMARY OF PRODUCT CHARACTERISTICS**

1. **NAME OF THE MEDICAL PRODUCT**
   DTP-HB10 (Combination vaccine)

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
   Each 0.5 ml of vaccine contains:
   - Purified Diphtheria toxoid: 20 Lf
   - Purified Tetanus toxoid: 7.5 Lf
   - Inactivated B Pertussis: 12 OU
   - HBsAg: 10 mcg
   - Aluminium Phosphate: 1.5 mg
   - Thimerosal: 0.05 mg

3. **PHARMACEUTICAL FORM**
   The vaccine is a homogeneous liquid containing DTP as purified diphtheria and tetanus toxoids and inactivated whooping cough organisms and Hepatitis B vaccine as a subunit viral vaccine containing highly purified, non infectious particles of Hepatitis B surface antigen (HbsAg). The Hep B is a DNA recombinant vaccine derived from HbsAg produced by DNA recombinant technology in yeast cells.

4. **CLINICAL PARTICULARS**

   4.1 Therapeutic indications
   - Prophylactic immunization against Diphtheria, Tetanus, Pertussis and Hepatitis B.

   4.2 Posology and method of administration
   **Immunization schedule**
   - In countries where pertussis is of particular danger to young infant, the combination vaccine should be started as soon as possible with the first dose given as early as 6 weeks, and two subsequent doses given at 4-week intervals.
   - The combined vaccine can be given safely and effectively at the same time as BCG, Measles and polio vaccines (OPV and IPV), Hib, Yellow Fever vaccines and vitamin A supplementation.
   - In countries where perinatal transmission of Hepatitis B is common the first dose of Hep B should be given as soon as possible after birth. In this case the combined vaccine should NOT be used. If perinatal transmission is uncommon, or if vaccination at birth is not feasible, the first dose can be given as the combination vaccine at 6 weeks. The second and third doses of the combined vaccine should then be administered one month apart at 10 and 14 weeks.

   **Administration**
   - The liquid 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, or into the deltoid muscles of older children or adults.(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 syringe and sterile needle should be used for each injection.
   - Once opened, multi-dose vials should be kept between +2°C and +8°C.
Multi-dose vials of DTP-HB 10 from which one or more doses of vaccine have been removed during and immunization session may be used in subsequent immunization session for up to a maximum of 4 week, provided that all of 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 vaccine are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water
- Aseptic technique has been use to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

4.3 Contraindication

Known hypersensitivity to any component of the vaccine, or a severe reaction to a previous dose of the combination vaccine or any of its constituents is an absolute contraindication to subsequent doses of the combination vaccine or the specific vaccine know to have provoked an adverse reaction. There are few contraindications to the first dose of DTP – fits or abnormality are contraindications to the pertussis component. In this case, the vaccines should not be given as a combination vaccine but DT should be given instead of DTP and Hep B given separately.

Immune deficiency

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic, should be immunized with combined vaccine according to standard schedules.

4.4 Special warnings and precautions for use

See the topic of posology and method of administration

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

The type and rate of severe adverse reactions do not differ significantly from DTP and Hep B vaccine reactions described separately.

For DTP, mild local or systemic reactions are common. Some temporary swelling, tenderness and redness at the site of injection together with fever occur in a large proportion of cases. Occasionally severe reactions of high fever, irritability and screaming develop within 24 hours of administration. Hypotonic-hyporesponsive episodes have been reported. Febrile convulsions have been reported at a rate of one per 12500 doses administered. Administration of acetaminophen at the time of and 4-8 hours after immunization decreases the subsequent incidence of febrile reactions. The national childhood encephalopathy (primarily seizures) following DTP immunization. However subsequent detailed reviews of all available studies by a number of groups, including the United States Institute of Medicine, the Advisory Committee on immunization Practices, and the pediatric associations of Australia, Canada, the United Kingdom and the United State, concluded that the data did not demonstrate a causal relationship between DTwP and chronic nervous system dysfunction in children. Thus there is no scientific evidence that these reactions in have any permanent consequences for the children.
Hepatitis B vaccine is very well tolerated. Some temporary swelling, tenderness and redness at the site of the injection occur in some individuals (about 12%). Other minor reactions such as malaise or fever occur in less than 2% of individuals. More serious reactions are rare; a causal relationship between more serious and the vaccine has not been established.

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
The combination 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 - Asia Co., Ltd. Bangkok, THAILAND

8. MARKETING AUTHORISATION NUMBER(S)
2C 10/60 (NB)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
October 4, 2017

10. DATE OF REVISION OF THE TEXT
May 9, 2018