SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
Vaxem-Hib

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Haemophilus influenzae type b (Hib) glycoconjugate vaccine is composed of bacterial capsular oligosaccharides conjugated to a carrier protein Cross Reacting Material 197 (CRM 197), non-toxic mutant of diphtheria toxin.
Each single dose of 0.5 ml contains:
Active ingredient: 10 micrograms of capsular oligosaccharide of *H. influenzae* type b conjugated to approximately 25 micrograms of CRM 197 protein.
Excipients: Single dose container: aluminum phosphate 1.36 milligram (adjuvant), sodium chloride, monobasic sodium phosphate, disodium phosphate dihydrate, Polysorbate 80, water for injections.
Multiple doses container: aluminum phosphate 1.36 milligram (adjuvant), thiomersal 0.05 milligram (preservative), sodium chloride, monobasic sodium phosphate, disodium phosphate dihydrate, Polysorbate 80, water for injections.

3. PHARMACEUTICAL FORM
Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Active immunization against invasive disease caused by Haemophilus influenzae type b in children from 2 months of age.

4.2 Posology and method of administration

*Posology*
Primary series: Under 13 months of age: Three 0.5 ml doses, with an interval of at least four weeks between doses, the first dose to be given not earlier than two months of age.
13 months of age and over. A single 0.5 ml dose.
Vaxem-Hib is not recommended for healthy children aged more than four years
Booster: Following completion of a primary series in which all three doses were administered before the age of 6 months, an additional (fourth) dose of Hib conjugate vaccine should be administered. The timing of the Hib conjugate booster dose should be in accordance with official recommendations.
Children who were primed with Vaxem Hib may be used to boosted with Vaxem Hib or with another Hib conjugated vaccines. Similarly, Vaxem Hib may be used to boost children who were primed with other Hib conjugate vaccine.

*Administration*
Vaxem Hib should be administered intramuscularly. In infants, Vaxem Hib should be administered in the anterolateral region of the thigh. Do not administer intravascularly. Patients with thrombocytopenia or bleeding disorders may be vaccinated by the subcutaneous route. Shake before use.
4.3 Contraindication
Hypersensitivity to any component of the vaccine.
Hypersensitivity reaction after previous administration of Hib vaccine.
As with other vaccine, vaccination should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor non-febrile infection, however, is not a contra-indication to vaccination.

4.4 Special warnings and precautions for use

Precautions
As with all vaccinations, appropriate medical treatment should be available for injection should an anaphylactic reaction occur. Recipients of the vaccine should remain under observation, until they have been seen to be in good health and not to be experiencing an immediate adverse reaction. Vaxem Hib should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. In these subjects the vaccine may be administered by deep subcutaneous injection.
Do not administer intravenously. Care should be taken that the needle of the syringe doses not penetrate the lumen of blood vessel.

Special warnings
In the presence of congenital or acquired immune deficiency, Vaxem Hib may be administered but a protective immune response may not be elicited. Although a limited immune response to the diphtheria toxin component may occur, vaccination with Vaxem Hib does not substitute for routine diphtheria vaccination.
Vaxem Hib does not elicit protection against diseases caused by other H. Influenzae serotypes and does not protect against meningitis caused by other pathogenic agents. Please inform your doctor if the person to be vaccinated ever had any side effect after the administration of any other vaccine or if the person to be vaccinated ever had any allergic reaction.

4.5 Interaction with other medical products and forms of interaction
Concomitant administration of Vaxem Hib with various vaccines containing the following antigens did not affect immune responses to these other antigens: diphtheria and tetanus toxoids, whole cell or acellular pertussis components, polioviruses (live attenuated), hepatitis B, or live attenuated measles, mumps and rubella virus.
As with other vaccines it may be expected that in patients receiving immunosuppressive therapy or patients with immunodeficiency, an adequate immune response may not be achieved. Different injectable vaccines must not be mixed in the same syringe and should be administered at different injection sites.

4.6 Pregnancy and lactation
Not applicable. Vaxem Hib is a pediatric vaccine.

4.7 Effects on the ability to drive and use machines
As Vaxem Hib is not intended for a use in adults, it is not intended for subjects who drive and operate machinery.

4.8 Undesirable effects
Vaxem Hib is an extremely well tolerated vaccine, however its administration may be associated with reactions.
The administration of any kind of vaccine may cause hypersensitivity reactions, rarely (usually less than one in ten thousand persons) including the anaphylactic reaction, whose characteristic symptoms are: serious and immediate hypotension, accelerated or retarded heartbeat, tiredness, unusual weakness, anxiety, restlessness, loss of consciousness, difficulty in breathing and deglutition, itching (especially at the sole of the foot and at the
palm of the hands) urticaria with or without angioedema (swollen and hitching skin areas localized more frequently at the extremities, at the external genitals and at the face, mainly at eye and lips regions), erythema (especially around the ears), nausea, vomit, abdominal pain, diarrhea.

The multiple dose presentation contains Thiomersal as preservative and allergic reactions could arise. The single dose presentation in preservative free.

In clinical trials with Vaxem Hib, the side effects that were seen are listed below by age group.

- **Very common side effect occurred in more than one in ten children**
- **Common side effects occurred in less that one in ten but more than one in hundred children**
- **Uncommon side effects occurred in less than one in hundred children.**

**In infants 2-6 months of age**
Very common: tenderness, redness or lumpiness at the injection site.
Unusual crying, irritability, being sick, diarrhea, change in eating habits, sleepiness, fever.
Common: tenderness at the site of injection.
Uncommon: screaming syndrome.

**In children 12-15 months of age**
Very common: unusual crying, irritability, being sick, diarrhea, change in eating habits, sleepiness, fever.
Common: tenderness at the site of injection.
Uncommon: rash. Redness or lumpiness at the site of injection

**Booster dose in children 16-20 months of age**
Very common: irritability
Common: being sick, diarrhea, change in eating habits and sleepiness.
Uncommon: agitation, unusual crying and rash.

**4.9 Overdose**
No cases of overdose have been reported.

**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
Excipients: Single dose container: aluminum phosphate 1.36 milligram (adjuvant), sodium chloride, monobasic sodium phosphate, disodium phosphate dihydrate, Polysorbate 80, water for injections.
Multiple doses container: aluminum phosphate 1.36 milligram (adjuvant), thiomersal 0.05 milligram (preservative), sodium chloride, monobasic sodium phosphate, disodium phosphate dihydrate, Polysorbate 80, water for injections.

6.2 Incompatibilities
N/A

6.3 Shelf life
Vaxem Hib has a shelf life of 2 years provided that the packaging is integral and the product correctly stored. Do not use the product after the expiry date.

6.4 Special precautions for storage
Store in the refrigerator at a temperature between +2°C and +8°C.
Do not freeze. Keep the medicine out of the reach of children.

6.5 Nature and contents of container
- 1 dose pre-filled syringe containing 0.5 ml of vaccine
- 1 dose vial containing 0.5 ml of vaccine
- 10 vials of 10 doses (5 ml of vaccine) each

6.6 Special precautions for disposal and other handling
N/A

7. MARKETING AUTHORISATION HOLDER
Biogenetech Co., Ltd.
18 Soi Udomsuk 37, Sukhumvit 103 Rd., Bangjak, Prakanong, Bangkok, 10260 THAILAND

8. MARKETING AUTHORISATION NUMBER(S)
1C 128/44 (N)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
February 3, 2005

10. DATE OF REVISION OF THE TEXT
February 13, 2008