SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
   ANATETALL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
   Purified tetanus toxoid adsorbed onto aluminium hydroxide.
   Each single dose of 0.5ml of Anatetall suspension for injection contains less than 40 I.U. of
   purified tetanus toxoid and aluminum hydroxide (1.5 mg)

3. PHARMACEUTICAL FORM
   Suspension for injection.

4. CLINICAL PARTICULARS

   4.1 Therapeutic indications
   Anatetall is indicated for primary active immunization against tetanus in children and adults.
   It is indicated for all subjects that suffered from sting or lacerate wound and from animal
   bites, contaminated by mold, dust, animal and/or human faeces, Tetanus immune prophylaxis
   also indicated in case of burns or for any lesion that presents sign of tetanus death or
   necrosis.

   4.2 Posology and method of administration

   Posology
   Vaccination of new born and children under 7 years of age
   For children under 7 years of age the use of vaccine containing tetanus component in
   combination with diphtheria (DT) and pertussis (DTP) and other antigens is recommended.
   Vaccination should be performed during the first year of life with three doses. The first dose
   should be administered during the third month of life (starting from the 8th week of age); the
   second dose during the 5th month of life, however not before 6 week from the first dose; the
   third dose within the 11th the 12th month of life. The first DT booster dose should be
   considered as an integral part of the primary vaccination and should be administered not
   before 4-5 years from the last dose. The following booster dose should be administered at
   ten year intervals.
   Vaccination of adults and of children over 7 years of age
   For adult and children over 7 years of age the vaccination schedule includes three doses of
   Anatetall at time 0, 1 month, 6-12 months and booster doses every 10 years.
   Longer intervals between administration in primary immunization cycle, if maintained within
   certain limits, have no impact on the efficacy of the immune response. For this reason it is
   not necessary to repeat primary vaccination cycle if the time elapses between the first and
   the second dose is less than 12 months and the time elapses between the second and the third
   dose is less than five years. Booster doses can be administered, without starting a new cycle,
   also when the interval is more than ten years.

   Treatment of injured subjects
   Careful surgical cleaning and antibiotic treatment should be performed independently from
   the immunization status of the subject. Immune prophylaxis must be performed according to
   the following instructions:
- Subject that received a complete vaccination cycle and one or more booster doses do not need additional treatment if the last administration has been performed not more than five years before, except when a high risk of infection is foreseen.
- In subject that received booster doses more than five years before, it is necessary to give a booster dose of Anatetall or of combined Tetanus and Diphtheria vaccine: tetanus immunoglobulins should not be administered.
- In subject with incomplete vaccination or that received booster doses more than ten years before, simultaneous administration of immunoglobulins and of one dose of vaccine is recommended, taking care to administer them in different sites of the body and with different syringes.
- In subject that were not vaccinated or anytime it is difficult to define the vaccination status, it is recommended simultaneous administration of immunoglobulins and of the first dose of vaccine according to the instructions described above.

**Method of administration**
The vaccine should be administered by intramuscular injection.
Do not administer by intravenous route

4.3 Contraindication
*Febrile illness or other acute infections:* Vaccination should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor non-febrile infection, such as cold or other minor infections of the upper respiratory tract, however, is not a contraindication, although temporary, to vaccination. Similarly vaccination should not be postponed in subjects undergoing treatment with corticosteroids for local use for systemic low dosage, as well as when cutaneous affections such as dermatitis, eczema or local cutaneous infections are present (Circ No9 of the Italian MoH date 26 March 1991).

*Immune status:* Patients undergoing immunosuppressive therapy may have a lower immune response. For this reason, except in case of urgency indications, vaccination should be deferred until one month after therapy is completed. In case of immediate risk, it is recommended to administer the vaccine and the immunoglobulins.

*HIV seropositivity,* by itself, is not a contra-indication to vaccination.

*Allergy:* any immediate hypersensitivity reaction or any neurological reaction after vaccination is to be considered an absolute contraindication to the administration of further dose of the vaccine. On the contrary, a case history of previous local side effect is not to be considered a contraindication.

Do not administration the vaccine in case of known hypersensitivity to any component of the vaccine formulation.

4.4 Special warnings and precautions for use
Before administration of any vaccine, appropriate precautions should be adopted to prevent possible adverse event, including record of the patient case history with regard to previous hypersensitivity reactions to this or to other vaccines.

As with any injectable vaccine, reactions of hypersensitivity cannot be excluded: 1:1000 adrenaline and corticosteroids should be available for any immediate allergic reaction.

In children suffering from cerebral or neurological disorder, or with an history of febrile convulsions, administration should be performed with caution in order to check their tolerance.

**The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunization series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a**
previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

4.5 Interaction with other medical products and forms of interaction
Tetanus vaccination is compatible with the performance of other immune practices. Anatetall can be administered simultaneously with human tetanus immunoglobulin, but the injections should be performed using different syringe and in different sites. Patients undergoing immunosuppressive therapy with high dose of corticosteroids or other immunosuppressive agents may have a lower immune response.

4.6 Pregnancy and lactation
Pregnancy or lactation dose not constitute a contraindication to Anatetall vaccination. To avoid neonatal tetanus, vaccination is particularly indicated for pregnant woman. Vaccination can be performed in the period from the beginning of the 4th month to the end the 8th month of gestation.
(art.2 of the Italian Law n.419 dated 20 March 1968 on the mandatory tetanus vaccination)

4.7 Effects on the ability to drive and use machines
Effects on ability to drive and operate machinery have not been reported.

4.8 Undesirable effects
Local reactions: redness, swelling and pain, sometimes with local linforadenopathy, are common after vaccine administration. Rarely, a nodule may be palpable at the injection site that can produce a sterile abscess. This nodule generally disappears in a few weeks. Local hypersensitivity reactions (rash, urticaria) rare in primary vaccination, have been observed in subjects who have received a large number of booster doses. Systemic reactions: fever, malaise, sleepiness, irritability, headache, myalgia, arthralgia, have been occasionally reported. Those symptoms are usually light and have a short duration. Rarely allergic reactions, also of the immediate type, and gastrointestinal disorders such as anorexia, vomit and diarrhea, have been reported. After administration of diphtheria and tetanus vaccines, central and peripheral nervous system disorders, including the Guillain-Barre syndrome and blood disorders such as thrombocytopenia, even if very rare, have been observed. Respiratory, thoracic and mediastinal disorders:
Apnoea in very premature infants (≤ 28 weeks of gestation) (see section 4.4)
The administration of any kind of vaccine may cause hypersensitivity reactions 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 itching skin areas localized more frequently at the extremities, at the external genitals and at the face, mainly at the eye and lips regions), erythema (especially around the ears), nausea, vomit, abdominal pain, diarrhoea. Consult doctor or pharmacist in case of any reactions different from the ones indicated above.

4.9 Overdose
No cases of overdose reactions have been reported.
5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic category: Tetanus Vaccine, Adsorbed ATC code J07AM01
Biological preparation for the immunization against tetanus, composed of a sterile suspension of tetanus toxoid adsorbed onto aluminium hydroxide.
The administration of the vaccine induces the production of humoral antibodies, capable to neutralize the toxins produced by Clostridium tetani.
The titer of antibodies and the duration of the immunity depends on the number of injections received; the administration of the recommended doses for a complete immunization guarantees an immunity protection that lasts for at least 10 years.

5.2 Pharmacokinetic properties
N/A

5.3 Preclinical safety data
N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Aluminium hydroxide 1.5 mg (adjuvant), sodium chloride, water for injections up to 0.5 ml.
Residue from the manufacturing process: formaldehyde not more than 0.001 mg

6.2 Incompatibilities
Not pertinent

6.3 Shelf life
The vaccine, if stored at a temperature between +2°C and +8°C, has a shelf life of three years.
The expiry date indicated on the box refers to the product in its integral packaging and correctly stored.

6.4 Special precautions for storage
Store in refrigerator at a temperature between +2°C and +8°C. Do not freeze.

6.5 Nature and contents of container
- 1 ampoule of neutral glass, Type I, containing 0.5 ml (1 dose) of vaccine
- 10 ampoule of neutral glass, Type I, containing 0.5 ml (1 dose) of vaccine each (packaging for hospitals)

6.6 Special precautions for disposal and other handling
No particular instruction is needed.

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 65/38
9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
   June 8, 1995

10. DATE OF REVISION OF THE TEXT
    October 22, 2008