1. NAME OF THE MEDICAL PRODUCT
Td pur

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 dose of vaccine (0.5 ml suspension) contains:
- Tetanus toxoid, adsorbed at least 20 IU.
- Diphtheria toxoid, adsorbed at least 2 IU.
- Aluminium hydroxide as adsorbent 1.5 mg
- Formaldehyde, salts, water for injection

3. PHARMACEUTICAL FORM
Td-pur is a whitish, turbid suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
a) Active immunisation against tetanus and diphtheria in persons from the age of 5 years onwards.
   b) Tetanus prophylaxis in cases of injury in persons from the age of 5 years onwards, with concomitant immunisation against diphtheria

4.2 Posology and method of administration

   Posology
   The national vaccination recommendations and/or the WHO guidelines are to be followed. Individuals of 5 years old and over receive an identical dose.
   1. Primary immunisation (for non-immunised persons or for those with no known record of vaccination).
      A total of 3 vaccinations with 1 dose (0.5 ml) each time:
      - Initial injection (from 5 years of age) 0.5 ml
      - 4 - 6 weeks later 0.5 ml
      - 6 - 12 months after the 2nd injection 0.5 ml

   2. Booster vaccinations
   It is recommended that, during adulthood, individuals who have received the complete primary immunisation course should have routine booster vaccinations against diphtheria and tetanus at 10 year intervals. When combination vaccines are used for booster vaccinations the indications and vaccination intervals of the other antigens in the vaccine should be taken into account in compliance with the current recommendations of the Standing Vaccination Committee.
   When diphtheria vaccination is indicated but protection against tetanus is adequate, a monovalent diphtheria vaccine should be used.
   Following complete primary immunisation, if there is a risk of diphtheria infection, a booster vaccination with the diphtheria adsorbate vaccine in keeping with the age or with appropriate combination vaccines should be undertaken if the last vaccination was more than 5 years ago.
   Controls of serum antibodies in cases of unclear vaccination status are not indicated.
Primary immunisation discontinued for many years need not be re-done but can be supplemented at any time with at least three vaccinations against diphtheria and tetanus (irrespective of the kind of vaccines previously used). In general there are no maximum intervals between vaccinations. Every vaccination recorded counts.

3. Immunisation after injury

a) Individuals completely protected against tetanus, whose last vaccinations were:
   - up to 5 years ago: no immediate vaccination necessary
   - 5-10 years: 0.5 ml Td-pur
   - more than 10 years ago: simultaneously 0.5 ml Td-pur + 250 IU tetanus immunoglobulin.

If the wounds are clean and minor, tetanus immunoglobulin need not be given.

b) When vaccinating a person with a known immune deficiency or on immunosuppressive treatment (an individual with congenital or acquired impairment of the body's defences), the success of the vaccination may be uncertain. In the event of injury, it is necessary to administer a simultaneous dose of tetanus immunoglobulin to these individuals.

Administration

The vaccine must not be administered into a blood vessel. (see "Special warnings and precautions for use")

The vaccine must be shaken before use.

Td-pur is administered as a deep intramuscular injection. In certain situations, e.g., haemorrhagic diathesis (increased tendency to bleed), Td-pur can also be administered as a subcutaneous injection (under the skin).

4.3 Contraindication

- People with acute diseases requiring treatment should not be vaccinated until at least 2 weeks after recovery (exception: vaccination after possible infection).
- Vaccinations with Td-pur should not in principle be carried out if transient thrombocytopenia (temporary fall in the number of platelets in the blood) or neurological (affecting the nervous system) complications occurred after an earlier diphtheria and/or tetanus vaccination.
- Vaccination inducing complications is a contraindication for any repeat vaccination with the same vaccine until the cause has been elucidated.
- This vaccine should not be injected if there is allergy to its constituents.
- For booster vaccinations in the event of injury there are very few absolute contraindications (known, severe allergic reactions to the constituents of the vaccine, particularly secondary reactions not limited to the site of injection). In these cases, tetanus vaccine alone should be given if there was intolerance to a previous diphtheria vaccination, and tetanus immunoglobulin alone, (250 IU administered twice with a 4 week interval between doses), if there was intolerance to the tetanus or diphtheria/tetanus vaccination.

4.4 Special warnings and precautions for use

The vaccine must not be administered into a blood vessel. Unintentional administration into a blood vessel may provoke reactions, which could be even as severe as shock. Suitable immediate measures to counteract shock must be taken.

Patients with congenital or acquired immune defect may be vaccinated against diphtheria and tetanus. The success of the vaccination may be uncertain.

4.5 Interaction with other medical products and forms of interaction

If given during immunosuppressive treatment (treatment impairing the body's own defences), the effect of the vaccine may be restricted or uncertain (cf. Posology).
The simultaneous administration of tetanus immunoglobulin, which may be necessary in the event of injury, should be into a different part of the body.

4.6 Pregnancy and lactation
If existing vaccination protection is inadequate, pregnant women should be vaccinated preferably in the 2nd or 3rd trimester against diphtheria. This applies in particular before journeys to countries where the disease is endemic and when exposure is suspected. Lactation is not a contraindication to the use of the vaccine. Breast-feeding is not a contraindication.

4.7 Effects on the ability to drive and use machines
N/A

4.8 Undesirable effects
If you observe side effects, especially any that are not mentioned in this package leaflet, please inform your doctor or pharmacist.
The frequency of side effects is defined as follows:
Very common \( \geq 10\% \)
Common \( \geq 1\% - < 10\% \)
Uncommon \( \geq 0.1\% - < 1\% \)
Rare \( \geq 0.01\% - < 0.1\% \)
Very rare \( < 0.01\% \), including isolated cases

Local reactions at the injection site
Very common: Erythema, Swelling, Pain, Induration, Itching
Very rare: Nodule at injection site, exceptionally filled with fluid

Systemic reactions

Body as a whole
Frequent: General malaise
Rare: Influenza-like symptoms (e.g. outbreaks of sweating, shivering, fever)

Muscles and joints
Very common: Myalgia
Frequent: Arthralgia

Gastrointestinal tract
Rare: Gastrointestional symptoms

Cardiovascular system
Rare: Transient vascular reactions

Blood and lymphatic system:
Common: Local lymphadenopathy
Very rare: Transient changes in blood count, such as thrombocytopenia

Immune system:
Rare: Allergic reactions (e.g. dyspnoea), short-term exanthema
Very rare: Allergic diseases of the kidney, associated with transient proteinuria

Nervous system
Very common: Headaches
Very rare: Diseases of the central or peripheral nervous system, such as increasing paralysis leading even to respiratory paralysis (Guillain-Barré syndrome), inflammation of a peripheral nerve plexus (plexus neuritis)
Side effects are more prevalent in hyperimmunised individuals (people with more than adequate vaccination protection).
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 hydroxide (adjuvant), formaldehyde < 0.001mg, salts, water for injections.

6.2 Incompatibilities  
N/A

6.3 Shelf life  
4 years

6.4 Special precautions for storage  
Td-pur must be stored between +2 and +8°C.  
Do not freeze.  
Do not use frozen vaccine.  
The preparation must not be used after the expiry date shown on the pack and on the container.  
Keep out of the reach and sight of children.

6.5 Nature and contents of container  
Pre-filled syringe (with/without needle) containing 0.5 ml suspension  
Pack of 10 pre-filled syringes (with/without needle) each containing 0.5 ml suspension

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)  
2C 9/48

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION  
January 28, 2005

10. DATE OF REVISION OF THE TEXT  
July 23, 2009