1. NAME OF THE MEDICAL PRODUCT

DIPHTHERIA AND TETANUS VACCINE ADSORBED FOR ADULTS AND ADOLESCENTS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml contains:

- Diphtheria Toxoid \( \leq 5 \text{ Lf} (\geq 2 \text{ IU}) \)
- Tetanus Toxoid \( \geq 5 \text{ Lf} (\geq 40 \text{ IU}) \)
- Adsorbed on Aluminium phosphate (AIPO\(_4\)) \( \leq 1.25 \text{ mg} \)

3. PHARMACEUTICAL FORM

Grayish – white suspensions

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For primary vaccination and revaccination of adults and adolescents, who are having contraindications of DTP.

Primary vaccination and revaccination of children older than 7 years. In order to prevent allergic reactions to the protein of Diphtheria toxoid, the quantity to the toxoid has been markedly reduced.

After a primary immunization course of either DTP or Td, adsorbed Td for adults may be used as a booster at intervals of approximately 10 years, but with a minimum of at least one year between doses. It can safely replace monovalent tetanus toxoid (TT) vaccine, including during pregnancy.

The vaccine can be safely and effectively given simultaneously with BCG, measles, Polio Vaccine (IPV and OPV), Hepatitis-B, Yellow fever Vaccine, Haemophilus influenzae-B and Varicella vaccine.

4.2 Posology and method of administration

The vaccine should be injected intramuscularly. The preferred site for injection is deltoid muscles. Care should be taken not to inject into the blood vessel or the skin. Only sterile syringes and needles should be used for each injection. The vaccine should be well shaken before use.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Td from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met:

- The expiry date has not passed.
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;

The vaccine should be visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

Two injections of 0.5 ml at least four weeks apart followed by a third injection 6 to 12 months later. The vaccine should also be given as a booster immunization every 5 to 10 years.

4.3 Contraindication

The vaccine should not be given to persons who showed a severe reaction to a previous dose of Diphtheria and Tetanus vaccine.

A history of systemic allergic or neurologic reactions following a previous dose of Td is an absolute contraindication for further use.

Immunization should be deferred during the course of an acute illness. Vaccination of persons with severe, febrile illness should generally be deferred until these persons have recovered. However, the presence of minor illnesses such as mild upper respiratory infections with or without fever should not preclude vaccination.

4.4 Special warnings and precautions for use

Single pediatric dose should not exceed 0.5 mg (0.5 ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis.

As with the use of all vaccines the vaccine should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions.

Efcorlin hydrochloride and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

Special care should be taken to ensure that the injection does not enter a blood vessel.

It is extremely important when the parent, guardian, or adult patient returns for the next dose in the series, the parent, guardian, or adult patient should be questioned concerning occurrence of any symptoms and/or signs of an adverse reaction after the previous dose.

- HIV INFECTION

Diphtheria and tetanus vaccine for adults and adolescents may be used in adults and adolescents with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using this vaccines in symptomatic or asymptomatic HIV infected adults and adolescents.

4.5 Interaction with other medical products and forms of interaction
If Td and TIG or Diphtheria Antitoxin are administered concurrently, separate syringes and separate sites should be used.

As with other intramuscular injections, use with caution in patients on anticoagulant therapy,
Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids used in greater than physiologic doses, may reduce the immune response to vaccines.

4.6 Pregnancy and lactation

4.7 Effects on the ability to drive and use machines

4.8 Undesirable effects

Reactions, are generally mild and confined to the site of injection. Some inflammation may occur together with transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each 0.5 ml contains:

Thiomersal 0.01%

6.2 Incompatibilities

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

The vaccine should be stored in a dry, dark place at a temperature between 2-8°C. Transportation should also be at 2-8°C. Do not freeze.

6.5 Nature and contents of container
6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER
   MASU CO., LTD.

8. MARKETING AUTHORISATION NUMBER (S)
   3/2536

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
   28 July 2004

10. DATE OF REVISION OF THE TEXT
    22 June 2012