1.6.1 Prescribing Information (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Diphtheria and Tetanus Vaccine Adsorbed For Adults and Adolescents

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single 0.5 ml human dose contains

Diphtheria Toxoid ≤ 5 Lf (≥ 2 IU)

Tetanus Toxoid ≥ 5 Lf (≥ 40 IU)

Adsorbed on Aluminium Phosphate, Al^{+++} ≤ 1.25 mg

Preservative: 0.005 % Thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

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 of the toxoid has been markedly reduced. After a primary immunisation course of either DTP or Td for adults may be used as a booster at intervals of approximately 10 years, but with a minimum of at leastone 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 and Yellow Fever Vaccine, Haemophilus Influenzae type b and Varicella vaccine vitamin A supplementation.

4.2 Posology and Method of Administration

Posology

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

Method of Inoculation

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 +2ºC and +8ºC. Multi-dose vials of Diphtheria and tetanus vaccine adsorbed for adults and adolescents vaccine from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07):

• The vaccine is currently prequalified by WHO;

• The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO;

• The expiry date of the vaccine has not passed;

• The vaccine vial has been, and will continue to be, stored at WHO - or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

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.

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 Warning and Precaution

ADRENALINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5mg (0.1 – 0.5 ml of 1:1000 injection) given s/c or i.m. Single dose should not exceed 1 mg (1ml). For infants and children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml / kg of 1:1000 injection). 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 vaccinees 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.

4.5 Interaction With other Medicinal Products, Other Interactions

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

Not Applicable

4.7 Effects On Ability To Drive And Use Machines

Not Applicable

4.8 Adverse Reactions

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

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: ATC Code: J07AM51

5.2 Pharmacokinetics Properties

Pharmacokinetic studies are not required for vaccines.

5.3 Preclinical Safety Data

No Data Available

6. PHARMACEUTICAL PROPERTIES

6.1 List of Excipients

Aluminium Phosphate (prepared usnig Aluminium Chloride, Tri-sodium Phosphate, Sodium Acetate and Sodium Chloride)

Thiomersal

Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

Thirty six months from date of manufacture.

6.4 Special Precautions for storage

The vaccine should be stored in dry and 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 Packaging

1 Dose Ampoule: Clear transparent USP type I ampoule

10 and 20 Dose Vial: Clear white tubular type I vial; sealed with rubber stopper and flip-off Aluminium cap.

6.6 Instructions regarding the preparation of medicinal products for its use and handling

Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

7 MARKETING AUTHORISATION HOLDER

SERUM INSTITUTE OF INDIA PVT. LTD.

212/2, HADAPSAR, PUNE-411028.

MAHARASHTRA, INDIA.

TELEPHONE: ++ 91-20-26602633 / 26993900 / 04
FAX: ++ 91- 20-26993924 / 26993921
E-MAIL: vijay.patil@seruminstitute.com

8 NUMBER IN THE REGISTER OF MEDICINAL PRODUCTS

NA

9 DATE OF AUTHORISATION OR LAST RENEWAL OF AUTHORISATION

NA

10 DATE OF REVISION OF TEXT

NA