SUMMARY PRODUCT CHARECTERISTICS

Diphtheria and Tetanus Vaccine Adsorbed (for adults and adolescents)

DESCRIPTION	Diphtheria and Tetanus Vaccine Adsorbed for adults and adolescents (Td) is prepared by combining purified diphtheria toxoid and purified tetanus toxoid. The antigens are adsorbed onto aluminum phosphate as adjuvant. Thiomersal is added as preservative. The vaccine has the appearance of a grayish suspension and does not contain any horse serum protein. Therefore, it does not induce sensitization to sera of equine origin. The vaccines meets the requirement of W.H.O and B.P when tested by the methods outlined in W.H.O TRS.980 (2014) and BP.
POTENCY	Each Single 0.5ml human dose contains Diphtheria Toxoid: ≤5Lf (≥2 UI) Tetanus Toxoid: ≥5Lf (≥40 UI) Adsorbed on Aluminum Phosphate , Al^{+++} ≤1, 25 mg Preservative: 0.01% Thiomersal
THERAPEUTIC INDICATIONS	For primary vaccination and revaccination of adults and adolescents who are having contraindication of DTP. For primary vaccination and revaccination children older than 7 years. In order to prevent allergic reactions to the protein of Diptheria toxoid, the quantity of the toxoid has been markedly reduced. After a primary immunization course of either DTP or vaccine, adsorbed Td for adults may be used as a booster at intervals of 10 years, but with a minimum of at least 1 year between doses. It can safely replace monovalet Tetanus Toxoid vaccine including during pregnancy. The vaccine can be safely and effectively given simultaneously with BCG, Measels, Polio Vaccine (IPV and OPV),Hepatitis B, Yellow fever vaccine, Heamophlus Influenzae type B, Varicella Vaccine and Vitamin A supplementation.
DOSAGE & METHOD OF ADMINISTRATION	Two injections of 0.5 ml at least 4 weeks apart followed by a third injection 6-12 months after the second dose. The vaccine should also be a booster immunization every 5-10 years. The vaccine should be injected intramuscularly. The preferred site for injection is deltoid muscles. Care should be taken not to inject into the blood vessels or the skin. Only the sterile syringes and needle 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 vaccine from which one or more doses of vaccines 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: 1. The expiry date has not passed. 2. The vaccines are stored under appropriate cold chain conditions. 3. The vaccine vial septum has not been submerged in water. 4. Aseptic technique has been used to withdraw all doses. 5. The vaccine vial monitor (VVM), if attach, has not reached discard point. 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.
CONTRAINDICATONS	The vaccine should not be given to persons who showed a severe reaction to a pervious dose of diphtheria tetanus toxoid. A history of systemic allergic or neurologic reactions following a pervious dose of DT is an absolute contraindication for further use.
SPECIAL WARNINGS & PRECAUTION FOR USE	Immunization should be deferred during the course an acute illness. Vaccination of persons with severe, febrily illness should generally be deferred until these persons have recovered. However, the presence of minor illness such as mild upper respiratory infections with or without fever should not preclude vaccination.
INTERACTION WITH OTHER MEDICAL	If DT and TIG or diphtheria antitoxin are administered concurrently, separate syringes and separate sites should be used. As with other intermolecular injections, use with

PRODUCTS & OTHER FORM OF INTERACTION	patients on anticoagulant therapy. Immuno suppressive therapies, including irradiation, antimetabolits, alkylaylating agents, cytotoxic drugs and corticosteroids used in greater than physiologic doses may reduced the immune response to vaccines.
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. In older children the local and general reactions may be more severe due to sensitivity to the diphtheria protein.
OVERDOSE	Single dose should not exceed 1mg (1ml).
STORAGE OF VACCINES	The vaccine should be stored in dry, dark place at a temperature between 2-8°C. Transportation should also be at 2-8°C. DO NOT FREEZE.
PRESENTATION	1 dose ampoule of 0.5 ml 10 dose vial of 5 ml 20 dose vial of 10 ml
MARKETING AUTHORIZATON HOLDER	Serum Institute of India Ltd.
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02540 BHU-DRA/B02541 BHU-DRA/B02542