SUMMARY PRODUCT CHARECTERISTICS

Diphtheria and Tetanus Vaccine Adsorbed (pediatric)

DESCRIPTION	Diphtheria and Tetanus Vaccine Adsorbed (DT) 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)
POTENCY	Each Single 0.5ml human dose contains: Diptheria Toxoid: ≤25Lf (≥30 UI) Tetanus Toxoid: ≥5Lf (≥40 UI) Adsorbed on Aluminium Phosphate , Al^{+++} ≤1, 25 mg Preservative: 0.01% Thiomersal
THERAPEUTIC INDICATIONS	The vaccine is recommended to use in childhood immunization instead of DTP vaccine when contraindications to the pertussis component exist. DT vaccine is recommended for children below 7 years of age; for persons 7 years and older, a special DT vaccine, containing a reduced amount of diphtheria toxoid is recommended. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatatis B, Yellow fever vaccine, Haemophilus influenzae B and Varicalla vaccine.
DOSAGE & METHOD OF ADMINISTRATION	The injection of 0.5ml at least 4 weeks apart followed by a fourth dose 6-12 months later. The vaccine should be injected intramuscularly. The preferred site for injection in infants and young children is the anterolateral aspect of the upper thigh or the deltoid muscle in the older children. Only sterile needles and syringes 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 DT from which one or more doses of vaccines have been removed during immunization session may be used in subsequent immunization sessions up to a maximum of 4 weeks, provided 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, febrile 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 PRODUCTS & OTHER FORM OF INTERACTION	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 patients on anticoagulant therapy. Immunosuppressive therapies, including irradiation, antimetabolits, alkylaylating agents, cytotoxic drugs and corticosteroids used in greater than physiologic doses may reduced the immune response to vaccines.
UNDESIRABLE	Reactions are generally mild and confined to the site of injection. Some inflammation

EFFECTS	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 pediatric dose should not exceed 0.5 mg (0.5ml).
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/B02730 BHU-DRA/B02731 BHU-DRA/B02732