SUMMARY PRODUCT CHARECTERISTICS

Diphtheria Tetanus Pertussis (Adsorbed)

DESCRIPTION	Diphtheria, Tetanus and Pertussis vaccine adsorbed is prepared by combining purified diphtheria toxoid, purified tetanus toxoid and *Bordetella pertussis* bacilli. The antigens are adsorbed on to aluminium phosphate as adjuvant. The vaccine has the appearance of grayish white suspension and does not contain any horse serum protein.
POTENCY	Each dose of 0.5 ml contains: Diphtheria Toxoid ……..≤ 25 Lf (≥ 30 IU) Tetanus Toxoid……≥ 5 Lf (≥ 40 IU) B. pertussis…….≤ 16 OU (≥ 4IU)
THERAPEUTIC INDICATIONS	For the primary immunization of infants above the age of six weeks and of pre-school children against Diphtheria, Tetanus and Whooping Cough. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever Vaccine, Haemophilus influenzae-B and Varicella vaccine.
DOSAGE & METHOD OF ADMINISTRATION	DTP vaccine should be injected intramuscularly. For the purpose of primary immunization it is recommended that 3 doses of 0.5 ml should be inoculated on 3 separate occasions at 4 to 6 weeks interval. The first dose should be given at approximately 6 weeks of age. Reinforcing injections of 0.5 ml should be given 12 months after the primary immunization and also between the ages of 4 to 6 years.
CONTRAINDICATONS	DTP Vaccine (Adsorbed) should not be administered to infants or children with high fever or other evidence of acute illness or infection. The presence of an evolving or changing neurological disorder is a contraindication to receipt of this vaccine. While data to support exclusion of Pertussis immunization because of a family history of convulsive or other neurological disorders are scarce, a personal or family history of central nervous system disease or convulsions is considered a contraindication to use of this vaccine. Occurrence of any of the following signs, symptoms or conditions following administration is a contraindication to further use of this product and/or pertussis vaccine as the single antigen: fever over 40°C (104°F); convulsion(s) with or without accompanying fever; alterations of consciousness; focal neurologic signs; screaming episodes; shock; collapse; thrombocytopenia purpura. DTP Vaccine (Adsorbed) should not be administered to children over six years of age or to adults because of the danger of reactions to diphtheria toxoid or to pertussis vaccine and because pertussis is less severe in these age groups than in infants and young children. The specific contraindications adopted by individual national health authorities should reflect a balance between the risk from the vaccine and the risk from the disease. Because the risk from the vaccine remains extremely low in comparison to the risk from the disease in many developing countries, authorities there may choose to offer immunization to children who are mildly to moderately ill or malnourished.
SPECIAL WARNINGS & PRECAUTION FOR USE	Individuals receiving corticosteroids or other immunosuppressive drugs may not develop an optimum immunologic response.
INTERACTION WITH OTHER MEDICINAL	If DTP and TIG or Diphtheria Antitoxin is administered concurrently, separate syringes and separate sites should be used. As with other intramuscular injections, use with

PRODUCTS & OTHER FORM OF INTERACTION	caution in patients on anticoagulant therapy. Immunosuppressive therapies, including irradiation, anti-metabolites, alkylating agents, cytotoxic drugs and corticosteroids used in greater than physiologic doses may reduce the immune response to vaccines.
PREGNANCY & LACTATION	No clinical data on use during pregnancies are available with this vaccine, as this vaccine is intended to use in Pediatrics only.
UNDESIRABLE EFFECTS	Mild, local reactions such as pain, tenderness, erythema, indurations are common and may be associated with temperature elevation (38-39°C) and an infiltration of 3 to 4 cm in diameter. Other reactions that may be observed include chills, irritability, persistent crying in infants and general malaise. Most reactions last for 24 to 48 hours: in such cases the use of antipyretics and in the case of local reaction, cold compresses should be considered. Occasionally a nodule may develop at the site of injection but this is without any harmful effects. More serious reactions such as fever above 40°C excessive screaming, and encephalopathic symptoms (e.g. convulsions) may also be observed but are extremely rare. By strict observance of the contraindications listed below the number of such complications will be reduced to a minimum.
STORAGE OF VACCINES	The vaccine should be stored in a dry, dark place at a temperature between 2°C - 8°C. Transportation should also be at 2°C - 8°C. DO NOT FREEZE.
PRESENTATION	1 dose vial plus diluent (0.5ml) 10 dose vial plus diluent (5ml) 20 dose vial plus diluent (10ml)
MARKETING AUTHORIZATON HOLDER	Serum Institute of India Ltd.
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02696 BHU-DRA/B02697 BHU-DRA/B02698