SUMMARY PRODUCT CHARECTERISTICS

Tetanus-Diphtheria (Td) Vaccine

DESCRIPTION	The vaccine contains purified tetanus and diphtheria toxoids, with reduced dose of diphtheria component. One dose of 0.5ml has a potency of less than 30IU of diphtheria toxoid, and not less than 40 IU of tetanus toxoids. The toxoids are adsorbed onto 3mg/ml Aluminium Phosphate. Thimerosal 0.1mg/ml is used as preservative. The vaccine is used for the active immunization of adults and children 7 years of age and older against diphtheria and tetanus.
POTENCY	Each single 0.5ml of human dose contains: Purified diphtheria toxoid 2 Lf Purified Tetanus Toxoid 7.5 Lf Aluminum Phosphate, 1.5mg. Preservative: 0.05mg Thiomersal
THERAPEUTIC INDICATIONS	Prophylactic immunization against Diphtheria and Tetanus
DOSAGE & METHOD OF ADMINISTRATION	A single 0.5ml dose of vaccine is recommended. The use of Td vaccine to replace other diphtheria and tetanus containing vaccines should be in accordance with official recommendation due to the low dose of diphtheria toxoid in vaccine. The use of vaccine for primary immunization and in pregnancy has not been evaluated. It may be given at the same time as measles, polio (OPV and IPV), Hepatitis B, Yellow fever vaccines and vitamin A supplementation. The vaccine vial should be shaken to homogenize the suspension. The vaccine should be injected intramuscularly in the upper arms. A sterile needle and sterile syringe should be used for each injection.
CONTRAINDICATONS	A second or subsequent dose of Td should not be given to an individual who suffers a severe reaction to the previous dose.
PREGNANCY & LACTATION	It is safe to give during pregnancy.
UNDESIRABLE EFFECTS	Some transactional tenderness and redness at the site of injection and occasionally fever may occur
STORAGE OF VACCINES	The vaccine should be protected from the light and stored and transported between 2-8°C. IT MUST NOT BE FROZEN. Once opened, multi dose vials should be kept between 2-8°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 session for up to maximum of 4 weeks, provided that all of the following conditions are met(as described in the WHO policy statement: the use of opened multi dose vials in subsequent immunization session, WHO/V&B/00.09) -The expiry date has not passed; - The vaccine are stored under appropriate cold chain condition; - The vaccine vial septum has not been submerged in water; - Aseptic technique has been used to withdraw all the dose - The vaccine vial monitor, if attached has not reached the discard point.
PRESENTATION	The vaccine comes in vial of 10 doses.
MARKETING AUTHORIZATON HOLDER	Manufacturer: Bio Farma, Indonesia

PRODUCT REGISTRATION NUMBER	BHU-DRA/B02666