SUMMARY PRODUCT CHARECTERISTICS

Bacillus Calmette-Guerin Vaccine I.P TUBERVAC (freeze dried)

DESCRIPTION	TUBERVAC (Bacillus Calmette-Guerin Vaccine I.P.) is a live freeze-dried vaccine derived from attenuated strain of mycobacterium bovis. TUBERVAC used for the prevention of tuberculosis. The vaccine meets the requirements of W.H.O. and I.P. when tested by the methods outlined in W.H.O., TRS. 745 (1987), 771 (1988) and I.P.
POTENCY	Each 1ml contains between: 1 x106 and 33 x 106 Colony Forming Units (C.F.U.).
THERAPEUTIC INDICATIONS	TUBERVAC should be given routinely to all infants at risk of early exposure to tuberculosis. In India the national policy is to administer BCG very early in infancy at birth. BCG administered early in life provides high level of protection particularly against severe forms of childhood tuberculosis and tubercular meningitis. In countries with low prevalence of tuberculosis, BCG vaccination should be restricted to high risk groups such as hospital personnel and tuberculin negative contacts of known cases of tuberculosis. The vaccine can be given simultaneously with DTP, DT, TT, Measles, Polio and Hepatitis B vaccines, but at a separate site.
DOSAGE & METHOD OF ADMINISTRATION	This vaccine is intended to be injected strictly via the intradermal route. The vaccination dose is 0.05 ml for children under one year of age including the new born and 0.1 ml for children over one year of age and adults of reconstituted vaccine given intradermally. The vaccine should be preferably given with a tuberculin syringe or 25G/26G sterile needle and syringe. Skin testing with tuberculin is not generally carried out before giving BCG, but when performed, those who are found to be positive reactors need not be immunized.
CONTRAINDICATONS	TUBERVAC is contraindicated in hypogamma-globulinemia, congenital immunodeficiency, sarcoidosis, leukaemia, generalised malignancy, HIV infections or any other disorder in which natural immune response is alterted, as also those on immunosuppressive therapy, corticosteroids, radiotherapy. In chronic eczema or other dermatological disease, the vaccine can be given in a healthy area of the skin. Keloid and lupoid reactions may also occur at the site of injection and such children should not be revaccinated. **SPECIAL CASE OF CHILDREN BORN TO HIV SEROPOSITIVE MOTHERS.** The obligatory passage of maternal antibodies of the lgG type through the placenta makes it impossible to interpret the serology of the child until the age of about 9-10 months (persistence of the maternal antibodies has been detected up to 14 months). It is therefore necessary to wait until the child has been found to be seronegative, as determined by immuno-transfer (Western Blot) with the support, if necessary, of techniques for detecting the viral genome, before confirming that the child is not infected. If the child is infected, BCG vaccine is contraindicated irrespective of the child's condition, given the potential risk of development of "BCG-itis" in the vaccinated child. The advice of a specialized medical team is required.
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM OF INTERACTION	TUBERVAC may be routinely given to any child exposed early to the risk of contact with the disease (tuberculosis). In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor. There is no indication to vaccinate women during pregnancy. Breast feeding can continue despite vaccination with BCG vaccine. As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's advice

	before using a medicinal product.
PREGNANCY & LACTATION	As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's advice before using a medicinal product.
UNDESIRABLE EFFECTS	A local reaction is normal. Following BCG vaccination, 2 to 3 weeks later a papule develops at the site of vaccination and increases slowly in size to a diameter of 4-8 mm in 5 weeks. It then subsides or breaks into a shallow ulcer covered with a crust. Healing occurs spontaneously in 6-12 weeks leaving a permanent, tiny round scar 2-10 mm in diameter. In rare cases an abscess may appear at the point of injection, or satellite adenitis, leading in exceptional cases to suppuration. Exceptional cases of lupus vulgaris at the injection site have been reported. Inadvertent subcutaneous injection produces abscess formation and may lead to ugly scars. A risk of generalised reaction to BCG exists in immuno-depressed individuals vaccinated with BCG or living in contact with a vaccinated individual.
STORAGE OF VACCINES	TUBERVAC should be stored in dark between 2º and 8ºC. Protect from light. The diluent should not be frozen, but should be kept cool.
PRESENTATION	20/ 10 doses vial plus diluent (1ml)
MARKETING AUTHORIZATON HOLDER	Serum Institute of India Ltd.
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02719 BHU-DRA/B02720