SUMMARY OF PRODUCT CHARACTERISTICS
BACILLUS CALMETTE - GUERIN VACCINE I.P.

1. NAME OF THE MEDICINAL PRODUCT:
Bacillus Calmette - Guerin Vaccine I.P., TUBERVAC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each 1 ml contains between:
1 x 10^6 and 33 x 10^6 Colony Forming Units (C.F.U)

Diluent : Sodium chloride injection I.P.

3. PHARMACEUTICAL FORM
TUBERVAC (BCG Vaccine I.P.) is a live freeze dried vaccine derived from attenuated strain of mycobacterium bovis. The vaccine meets the requirements of WHO and I.P.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
TUBERVAC is used for the prevention of tuberculosis

4.2 Posology and method of administration
This vaccine is indented to be injected strictly via the intradermal route. Universal Immunization Programme (UIP) of Government of India recommends 0.05 ml for children under one month of age and 0.1 ml for children over one month of age and adults of reconstituted vaccine given intradermally. The vaccine should be given preferably with 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.

4.3 Contraindications
TUBERVAC contraindicated in hypogamma-globuhnemia, congenital immunodefldency, sarcoidosis, leukaemia , generalised malignancy, HIV infections or any other disorder in which natural immune response is altered , 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.
4.4 Special warnings and precautions for use

SPECIAL CASE OF CHILDREN BORN TO HIV SEROPOSITIVE MOTHERS.

The obligatory passage of maternal antibodies of the IgG type through the placenta makes it impossible to interpret the serology of the child until the age of about 9-10months (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 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.

4.5 Interaction with other medicinal products and other forms 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 severer medicinal products any other ongoing treatment should be systematically reported to your doctor.

4.6 Pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

It is assumed that BCG vaccine has no effect on driving skills or the capability to operate machines.

4.8 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
generalized reaction to BCG exists in immunodepressed individuals vaccinated with BCG or living in contact with a vaccinated individual.

4.9 Overdose
No cases of overdosing have been reported.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Various clinical trials performed to assess the safety and efficacy of the vaccine proved that the vaccine is safe and efficacious.

5.2 Pharmacokinetic properties
Not applicable for vaccines.

5.3 Preclinical safety data
Not available

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
1.5% Sodium Glutamate

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months from the date of last satisfactory potency test, if stored in a dark place at a temperature between 2-8°C.

6.4 Special precautions for storage
24 months from the date of last satisfactory potency test if stored in a dark place at recommended temperature.

6.5 Nature and contents of container
4mL USP Type-I, tubular, amber coloured glass vial.

6.6 Special precautions for disposal
Once vaccine has been administered, the injection equipment and vaccine containers should be disposed of according to the standard procedures for medical waste.
7. MARKETING AUTHORISATION / PREQUALIFICATION HOLDER

SERUM INSTITUTE OF INDIA LTD,

212/2, Hadapsar, Pune – 411028, Maharashtra, INDIA.
Telephone: ++ 91-20- 26993900
Fax: ++ 91- 20-26993924 / 26993921
Website: www.seruminstitute.com

8. MARKETING AUTHORISATION NUMBER(S)

Drug Mfg. License. No. 10 (in Form 28-D) granted by State licensing Authority (Food and Drug administration) and Central License Approving Authority (Drug Controller General of India)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

   Date of first authorisation: 18.10.2001
   Date of renewal of the Authorisation: 01.01.2012

01/2014