SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Bacillus Calmette-Guerin Vaccine (Freeze Dried) I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Freeze dried Bacillus Calmette - Guerin vaccine is a preparation of the bacteria derived from the culture of attenuated *Mycobacterium bovis* BCG with Monosodium L-glutamate (1.5%) as stabilizer. The strain used is *Mycobacterium bovis* BCG Danish-1331. Each vial contains 1.5 - 6 x 10^6 CFU of *Mycobacterium bovis* BCG.

Name of ingredient	Spec. Target Conc.	Qty / Dose	Used as
Mycobacterium bovis Bacillus Calmette-Guerin Danish-1331	0.15 – 0.60 million CFU/dose	0.1 ml/dose For children aged between 1 month to 1 year.	Antigen/ Immunogen
Monosodium L-glutamate	1.5 %	0.3 mg/dose	Stabilizer

This is a multi-dose preparation consisting of 10 doses per vial. Supplied with diluent sodium chloride I.P. (0.9% w/v).

3. PHARMACEUTICAL FORM

Drug Substance

The final bulk of concentration (10mg/ml) contains 8.0 – 20.0 x 10^6 CFU/ml of *Mycobacterium bovis* BCG prepared as per Indian pharmacopoeia.

Drug Product

Freeze Dried Bacillus Calmette - Guerin vaccine I.P. (10 doses). White crystalline powder on reconstitution with diluent Inj. sodium chloride forms a slightly turbid suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) induces cell-mediated immunity against tuberculosis in children.

4.2 Posology and method of administration

The recommended dose is 0.05ml single dose for children below one month and 0.1ml single dose for children above one month up to one year of age.

Reconstitute with entire volume of diluent Inj.Sodium chloride I.P supplied. The vaccine should be injected strictly intradermally by the trained vaccinator. The preferred site for intradermal injection is the deltoid region of upper arm.

4.3 Contraindications

The vaccine should not be administered to children known to be hypersensitive to any component of the vaccine. Bacillus Calmette - Guerin vaccine is contraindicated in those with cell-mediated immune deficiency. Keloid and Lipoid reactions may occur at the site of injection and such children should not be revaccinated.

Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) should not be administered to children with past history of tuberculosis or those who are receiving anti-tuberculosis drugs. HIV-infected, non-symptomatic infants should be immunized with BCG vaccine according to standard schedules. Infants with clinical (symptomatic) AIDS should not receive BCG vaccine.

The vaccination should be postponed in children suffering from acute severe febrile illness or with generalized infected skin conditions. The vaccination should not be administered to children whose mothers are undergoing immunosuppressive treatment i.e. children with exposure from both in utero or via breastfeeding.

4.4 Special warnings and precautions for use

Although anaphylaxis is rare, facilities for its management should always be available during vaccination. The patients should be observed for an allergic reaction for up to 15-20 minutes after receiving immunization.

Administering the vaccine too deep increases the risk of discharging ulcer, lymphadenitis and abscess formation. Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) should only be administered by personnel trained in the intradermal technique.

4.5 Interaction with other medicinal products and other forms of interaction

Bacillus Calmette - Guerin vaccine may be given concurrently with inactivated or live vaccines, including combined measles, mumps and rubella vaccines.

When concomitant administration of other vaccines is required, the vaccines should be administered at different injection sites. If not given at the same time, an interval of not

less than four weeks should normally be allowed to lapse between the administrations of any two live vaccines.

It is advisable not to give further vaccination in the arm used for BCG vaccination for 3 months because of the risk of regional lymphadenitis.

4.6 Pregnancy and lactation

Although no harmful effects to the foetus have been associated with BCG Vaccine, vaccination is not recommended during pregnancy or lactation.

However, in areas with high risk of tuberculosis infection, BCG may be given during pregnancy or lactation if the benefit of vaccination outweighs the risk as per the advice of the physician.

4.7 Effects on ability to drive and use machines

Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) is usually given to only children. Anyhow if adults gets the vaccine, it produces no or negligible effect on the ability to drive and use machines.

4.8 Undesirable effects

A local reaction at the vaccination site is normal after vaccination with Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried).A small tender red swelling appears at the site of the injection which gradually changes to a small vesicle and then an ulcer in 2-4 weeks. The reaction usually subsides within two to five months and in practically all children leaves a superficial scar 2-10 mm in diameter.

Rarely nodule may persist and ulcerate. Occasionally enlargement of auxiliary lymph may appear in 2-4 months following immunization. Inadvertent subcutaneous injection produces abscess formation and may lead to retracted scars. Immediately consult a healthcare professional if infection such as suppurative lymphadenitis occurs at the site of vaccination.

4.9 Overdose

Over dosage increases the risk of local infection at the site of vaccination and may lead to excessive scar formation. Gross over dosage increases the risk of undesirable BCG complications.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Vaccines

The vaccine elicits a cell-mediated immune response that confers a variable degree of protection to infection with *M. tuberculosis*. The duration of immunity after BCG vaccination is not clearly known, but there are some indications of a waning immunity for till 10 years and more. Vaccinated persons normally become tuberculin positive after 6 weeks.

5.2 Pharmacokinetic properties

Not relevant for vaccines

5.3 Preclinical safety data

Not applicable, as the vaccine is being used for more than seven decades in humans with excellent safety records.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monosodium L-glutamate - stabilizer

Sodium chloride solution I.P. – Diluent

6.2 Incompatibilities

Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) should not be mixed with other medicinal products.

6.3 Shelf life

The shelf life of Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) is 24 months from date of manufacture if stored at 2 to 8°C in dark.

Reconstituted BCG vaccine is recommended to be used immediately and not later than 3 hours after reconstitution.

6.4 Special precautions for storage

Bacillus Calmette - Guerin vaccine I.P. (Freeze Dried) should be stored at a temperature

between 2 to 8°C away from light. It is even more stable if stored as low as -20°C. The diluent should not be frozen but should be kept in cool.

6.5 Nature and contents of container

Freeze dried powder in 2R amber Type I neutral glass vial with 13 mm Grey Bromo butyl rubber stoppers and Aluminium flip off seals. 50 vials of vaccine packed in Inner carton box (3 ply).

Diluent Inj.Sodium chloride in transparent glass ampoules packed separately, 50 Ampoules per inner box (3ply).

6.6 Special precautions for disposal

Any unused product/waste material should treated as biomedical waste and disposed in accordance with local requirements.

7. MARKETING AUTHORISATION

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8. MARKETING AUTHORISATION NUMBER(S)

Market Authorisation No. MF/BIO/19/000036

9. DATE OF FIRST AUTHORISATION

Date: 26th July 2019.

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