BCG INSERT

BCG VACCINE (FREEZE-DRIED)
Active Immunizing Agent

FOR INTRACUTANEOUS INJECTION

BCG Vaccine (Freeze-Dried) for intracutaneous administration, as prepared by Aventis Pasteur Limited, is made from a culture of an attenuated strain of living bovine tubercle bacillus (Bacillus Calmette-Guerin). It is supplied as a freeze-dried product ready for immediate use following reconstitution with the accompanying diluent, which consists of sterile phosphate-buffered saline. The manufacturing and testing procedures used by Aventis Pasteur Limited for freeze-dried BCG Vaccine comply with the recommendations of WHO as stipulated in WHO Technical Report Series No. 638, 1979: Revised Requirements for Dried BCG Vaccine.

INDICATIONS

BCG Vaccine should be administered only to individuals who have NOT been infected by the tubercle bacillus or to individuals who are tuberculin negative.

BCG vaccination has NO value in the treatment of tuberculous disease.

Administration of BCG Vaccine (freeze-dried) is recommended for:

(a) individuals who are repeatedly exposed to untreated or inadequately treated active tuberculosis;
(b) communities or groups of persons with high rates of infection, including Indian, Metis and Inuit children, in which other control measures have proved ineffective;
(c) health workers at considerable risk of exposure to unrecognized infectious pulmonary tuberculosis or who handle tubercle bacilli or potentially infectious specimens in a laboratory;
(d) Newborn infants whose mothers have infectious tuberculosis at the time of delivery, although isoniazid (INH) prophylaxis is referred to avoid the necessary separation of mother and infant when BCG is used. However, BCG is recommended if the infecting strain is INH resistant or if compliance with a program of INH prophylaxis cannot be assures. BCG may also be considered for the infant after INH prophylaxis is completed, provided chest radiographs and tuberculin test are negative [2].

CONTRAINDICATIONS

BCG Vaccine (Freeze-Dried) is contraindicated for individuals suffering from general malaise or conditions such as measles, whooping cough, eczema, furunculosis, atopic dermatitis or other exudative or inflammatory dermatologic conditions. BCG vaccination should not be combined with vaccination against other diseases. After vaccination with another antigen, there should be a sufficient time interval to allow any reaction that results to subside before BCG Vaccine is administered. Conversely, if BCG Vaccine is given first, vaccination with other antigens should not be carried out until the reaction to the BCG Vaccine has subsided.

BCG Vaccine (Freeze-Dried) should not be administered to the following:

(a) Individuals with primary immunodeficiency: e.g., agammaglobulinaemia, dysgammaglobulinaemia, hypogammaglobulinaemia, and symptomatic HIV (Human Immunodeficiency Virus [HTLV-|||/LAV]) infections
(b) Individuals undergoing treatment with immunosuppressive agents of any kind.
(c) Children and young adults who are immunosuppressed in association with AIDS or other clinical manifestation of HIV (Human Immunodeficiency Virus [HTLV-|||/LAV]) infection.[3]

WARNING

BCG vaccination has NO value in the treatment of tuberculous disease.

PRECAUTIONS

Administer BCG Vaccine (Freeze-Dried) intracutaneously do not inject subcutaneously.

The vaccinated person should, if possible, be kept away from all known tuberculous contacts or suspects until the sensitivity to tuberculin is verified which is usually within three months.

Although no harmful effects of BCG Vaccine on the foetus have been observed, vaccination of women during pregnancy is not recommended unless there is an excessive risk of unavoidable exposure to infective tuberculosis.

ADVERSE REACTIONS

Intracutaneous vaccination produces a small indurated papule in one to three weeks. In 39% of vaccinated newborns, this induration was ten to fifteen milimetres in diameter. Ulceration my follow, though with this strain and the proper administration technique ulceration is usually minimal and cold abscesses not observed. If small cold abscesses should appear, spontaneous resorption usually occurs. [4] In a few instances the abscess will soften and may spontaneously ulcerate. If an abscess does form, DO NOT puncture. Enlargement of the regional lymph glands may occasionally deveiop after vaccination. Some enlargement of the regional lymph nodes usually accompanies the lesions at the vaccination site. This was observed in 25% in a recent study in newborn infants. [4] Spontaneous regression usually occurs after a period of several months. If, however, perforation and persistent suppuration accompany enlargement of the regional lymph glands, anti-tuberculous chemoprophylaxis is indicated. **Surgical excision of the lymph glands is not recommended.**

DOSAGE AND ADMINISTRATION

The freeze-dried vaccine is reconstituted by introducing the diluent supplied into the vial of vaccine. (See instructions for reconstitution.)

Cleanse the outer surface of the upper arm with alcohol and allow to dry. Using a 1.0 mL syringe with a 26-gaude needle, inject the recommended dose of reconstituted vaccine indicated below into the most superficial layers of the skin (intracutaneously) at one site.

The bevelled side of the needle should face upwards.

The recommended dose for newborns and infants is 0.05 mL (0.05 mg). Children over 12 months of age and adults should be given the 0.1 mL (0.1 mg) dose. DO NOT INJECT SUBCUTANEOUSLY.[5,6]

Reconstitution of Freeze-Dried Vaccine and Withdrawal from Rubber – Stoppered Vial

DO NOT REMOVE THE RUBBER STOPPER FROM THE VIAL.

Apply a **sterile** piece of cotton moistened with a suitable antiseptic to the surface of the rubber stopper of the vials of diluent and vaccine. Allow the antiseptic to act for at least 5 minutes. Draw into a **sterile** syringe a volume of air equal to the volume of the diluent in the vial. Pierce the centre of the rubber stopper in the vial containing the diluent with the **sterile** needle of the syringe, invert the vial, slowly inject into it the air contained in the syringe, and, keeping the point of the needle immersed, withdraw into the syringe 1.5 mL of the diluent supplied. Then holding the syringe-plunger steady, withdraw the needle from the vial. Inject this volume of diluent into the vial of freeze-dried vaccine. Shake the vial gently until a fine, even suspension results. Withdraw the required dose of the reconstituted vaccine into the syringe.

REVACCINATION

If an individual remains tuberculin negative to the Mantoux test for 3 months or longer after vaccination, it is advisable to repeat the vaccination. The development of tuberculin sensitivity as measured by the Mantoux test confirms that the vaccine has established a primary infection in that individual.

Where BCG vaccination has been followed by a satisfactory level of tuberculin sensitivity a few months after vaccination, there is no current indication that revaccination is necessary within 5 to 10 years. In areas where young children are vaccinated, a second vaccination is sometimes given between the ages of 12 to 15 years. [5,7]

INTERPRETATION OF TUBERCULIN TEST

"After BCG vaccination, it is usually not possible to distinguish between a tuberculin reaction caused by virulent supra-infection and one resulting from persistent postvaccination sensitivity. Therefore, caution is advised in attributing a positive skin test to BCG (except in the immediate postvaccination period), especially if the vaccinee has recently been exposed to infective tuberculosis." [2,8]

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STORAGE

The freeze-dried vaccine should be kept in a refrigerator at a temperature of NOT more than 8°C. The vaccine should not be used after the expiration date marked on the vial, otherwise it may be inactive. **The vaccine should be used immediately after reconstitution and any reconstituted vaccine not used within 8 hours MUST be discarded.** The reconstituted vaccine should be maintained at 4°C.
At no time should the freeze-dried or reconstituted vaccine be exposed to sunlight, direct or indirect. Exposure to artificial light should be kept to a maximum. [9]

HOW SUPPLIED

BCG Vaccine (Freeze-Dried) is supplied in packages containing a multi-dose vial and accompanying diluent.

REFERENCES

1. WHO Expert Committee on Biological Standardization, 30th Report. Revised requirements for dried BCG vaccine (requirements for biological substances no. 11) (revised 1978). WHO Tech. Rep. Ser. 1979; 638:116-146.
2. National Advisory Committee on Immunization. A guide to immunization for Canadians [Ottawa]: Published by the Authority of the Minister of National Health and Welfare, 1984:25-6.
3. Recommendation of the Immunization Practices Advisory Committee (ACIP): Immunization of Children Infected with Human T-Lymphotropic Virus Type |||/Lymphadenopathy-Associated Virus. MMWR 1986;35:595-605.
4. Clinical Trials Colombia and Chile 1984. Data on file at Aventis Pasteur Limited.