

# BCG Vaccine (Freeze Dried)

## *Injection suspension*

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### **Presentation**

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BCG Vaccine (Freeze-Dried) for intracutaneous administration, as prepared by Connaught Laboratories Limited, is made from a culture of an attenuated strain of living bovine tubercle bacillus (*Bacillus Calmette-Guérin*). It is supplied in a multi-dose vial and is ready for immediate use following reconstitution with the accompanying diluent, which consists of sterile phosphate-buffered saline.

This vaccine fulfils WHO Requirements for Dried BCG Vaccine.

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### **Uses**

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#### ***Indications***

BCG is indicated for active immunisation against tuberculosis.

#### **Administration of BCG Vaccine (Freeze-Dried) is recommended for individuals:**

who comprise a group in which an excessive rate of infections can be demonstrated. (Such groups might exist among those without a regular source of healthcare.) or

who are repeatedly exposed to persistently untreated or ineffectively treated patients with sputum-positive pulmonary tuberculosis, or

who are health workers at increased risk of repeated exposure, especially those working in institutions serving major urban population centres in which the endemic prevalence of tuberculosis is relatively high.

BCG Vaccine should be administered to all infants at risk of early exposure to the disease.

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### **Dosage and Administration**

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The freeze-dried vaccine is reconstituted to a concentration of 1 mg BCG/mL by introducing the diluent supplied into the vial of vaccine. (See instructions for reconstitution).

Using a 1.0 mL syringe with a 26 gauge needle, inject the required dose of reconstituted vaccine into the most superficial layers of the skin (intracutaneously) at one site. Do not inject subcutaneously. The bevelled side of the needle should face upwards.

For newborns and infants up to 12 months of age, inject 0.05 mL. For children over 12 months of age and adults, inject 0.1 mL. Administer BCG Vaccine (Freeze-Dried) intracutaneously; do not inject subcutaneously.

## BCG DATA SHEET

### **Reconstitution of Freeze-Dried Vaccine and Withdrawal from Rubber Stopped 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 vial of vaccine. Holding the plunger of the syringe containing the diluent, pierce the centre of the rubber stopper in the vial and inject the required volume of diluent into the freeze-dried vaccine. The required volume for reconstitution is 1.5 mL for the 10 dose vial. Then, holding the syringe plunger steady, withdraw the needle from the vial. Shake the vial gently until a fine, even suspension results. Avoid foaming since this will prevent withdrawal of the proper dose. Withdraw the required dose of the reconstituted vaccine into the syringe. (Refer to Dosage and Administration).

A separate sterilized syringe and needle should be used for each individual patient to prevent transmission of hepatitis and other infectious agents.

Jet injectors do not generally provide a reliable dose of BCG and are best avoided.

### **Revaccination:**

After vaccination with BCG 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.

### **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.

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## **Contraindications**

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Keloid and lupoid reactions may occur at the site of injection and such children should not be revaccinated.

Individuals suffering from general malaise or conditions such as measles, whooping cough, eczema, furunculosis, atopic dermatitis or other exudative or inflammatory dermatologic conditions should not be vaccinated with BCG Vaccine (Freeze-Dried).

BCG vaccine must not be combined with other antigens (for example, diphtheria, typhoid fever and tetanus) in the same syringe; however, it may be administered at the same time as other vaccines provided they are injected SEPARATELY and at different sites.

BCG vaccine should not be administered to individuals with known natural or acquired immuno-deficiency conditions. The vaccine should not be administered to individuals receiving immunosuppressant therapy. The vaccine is contraindicated in those with cell-mediated immune deficiency.

Skin testing with tuberculin is not generally carried out before giving BCG Vaccine, but when performed, those who are found to be positive reactors need not be immunized.

Keloid and lupoid reactions may occur at the site of injection and such children should not be revaccinated.

### ***Human Immunodeficiency Virus (HIV) Infected Persons***

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The specific contraindications adopted by individual national health authorities should reflect a balance between the risk from the vaccine and the risk from the disease. Because the risk from the vaccine remains extremely low in comparison to the risk from the disease in many developing countries, authorities there may choose to offer immunization to children who have particular medical conditions.

HIV infected, non-symptomatic persons should be immunized with BCG Vaccine according to standard schedules. Persons with clinical (symptomatic) AIDS should not receive BCG Vaccine.

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### Warnings and Precautions

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BCG Vaccination has NO value in the treatment of tuberculosis disease.

#### 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.

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

#### Use in Pregnancy:

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.

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### Adverse Reactions

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Intracutaneous vaccination produces a small indurated papule in one to three weeks. In some cases a cold abscess may appear at the site of injection. Spontaneous resorption usually occurs. In a few instances the abscess will soften and may spontaneously ulcerate. In practically all children, the reaction usually leaves a superficial scar 2-10 mm in diameter.

Inadvertent subcutaneous injection produces abscess formation and may lead to ugly retracted scars. Do not administer subcutaneously.

Enlargement of the regional lymph glands may occasionally develop after vaccination. Spontaneous regression usually occurs after a period of several months. If abscesses of the lymph glands develop they can be punctured only if they are soft and fluctuating; anti-tuberculous chemoprophylaxis should be started immediately. Surgical excision of the lymph glands is not recommended.

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### Overdosage

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There are no reports of overdosage.

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### Pharmaceutical Precautions

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BCG Vaccine should be stored and transported between 2° and 8°C. Diluent should be stored in a cool place. When distribution or administration is not imminent, it is advisable to maintain storage of lyophilised vaccine (but not diluent) at temperatures of -20°C. Protect from light. Stability data indicate that potency is maintained when the vaccine is held between 2° and 8°C through to expiry date.

After reconstitution with the diluent supplied, store at 2-8°C. Any reconstituted vaccine not used within 8 hours MUST be discarded using methods suitable for biohazardous material. Any reconstituted product which exhibits flocculation or clumping that cannot be dispersed with gentle shaking should not be used..

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 minimum.

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### Package Quantities

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BCG Vaccine (Freeze-Dried) is supplied in packages containing a 1.5 mg vial and accompanying diluent (1.5 mL) vial. When reconstituted as directed the vaccine contains between 8 x 10<sup>6</sup> and 32 x 10<sup>6</sup> colony forming units per mL of product.

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### Medicine Classification

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Prescription Medicine

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### Further Information

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### Manufacturer

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**Sanofi Pasteur Limited**  
Toronto, Ontario, Canada

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### Distributor

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Australia:  
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**Date of Preparation**

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09 February 2012