

BCG VACCINE, FREEZE-DRIED

Vaccinum Tuberculosis (BCG) Cryodessicatum

DESCRIPTION

Freeze-Dried BCG Vaccine is a dried preparation containing live bacteria derived from an attenuated strain of *Mycobacterium bovis* Bacillus of Calmette and Guerin, known as BCG, intended for intradermal injection. It is used for the prevention of tuberculosis. It contains Sodium L-glutamate as a stabilizer. The vaccine meets the requirements of WHO for dried BCG vaccine (Requirements for Biological Substances No 11, formulated by WHO Expert Committee of Biological Standardization, Technical Report Series, No 745, 1987; 771, 1988).

COMPOSITION

This is a multidose container. After reconstitution with 1 ml diluent each single 0,05 ml paediatric dose contains approximately 0,025 mg moist weight of BCG and between 0.75-3,0 x 10⁵ viable units. Each paediatric dose contains 0.15mg Sodium L-glutamate monohydrate as stabilizer.

Diluent composition: Each single 0,05 ml paediatric dose contains 0.45mg Sodium chloride and water for injection to 0.05ml.

INDICATIONS

For the primary immunization of infants at birth and immunization or reimmunization of children and adults who have reacted negatively to the usual tuberculin tests.

ADMINISTRATION

For infants under one year of age, 0,05 ml of the reconstituted vaccine should be given intradermally. For others, the dose is 0,1 ml, again given intradermally. The use of a special tuberculin syringe and a sterile 26-gauge needle is recommended for each injection, so that exact dose can be administered. A sterile syringe and a sterile needle should be used for the reconstitution and for each injection. The skin should not be cleaned with antiseptic. Jet injections do not generally provide a reliable dose and should not be used. Prior to use, the bacterial mass should be shaken so that it falls to the bottom of the ampoule. Special care is needed in opening the ampoule and reconstituting the vaccine gently with the sterile diluent provided, so that the vaccine is not blown out of the ampoule. The liophilizate must be reconstituted by adding the entire content of the supplied container of diluent to the vaccine ampoule. The vaccine powder should be completely dissolved in the diluent. Following reconstitution, the vaccine should be inspected visually for any foreign particulate matter prior to administration. If observed, the vaccine must be discarded. A site frequently used for vaccination is the region over the distal insertion of the deltoid muscle, about one third down the left upper arm. The needle should be introduced with its aperture upwards. If the vaccine vial monitor is present, it is removed on reconstitution. Because of sensitivity to daylight, the vaccine must be kept in the dark. When withdrawals are made from the ampoule, the vaccine may only be exposed to the light for the minimum period of time. If not used immediately after reconstitution, the vaccine should be kept at 2°C-8°C, and protected from light (not more than 6 hours). Any opened ampoule remaining at the end of the immunizing session (maximum 6 hours) **MUST BE DISCARDED**. The diluent supplied is specially designed for use with this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or from other manufacturers. Water for injection may NOT be used for this purpose. Using an incorrect diluent may result in damage to the vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be cooled between +2°C and +8°C before reconstitution. 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.

IMMUNIZATION SCHEDULE

BCG should be given routinely to all infants at birth. There is no proven benefit of repeated BCG vaccination against TB. For maximum protection, this vaccine should be given as soon after birth as possible. It can be given at the same time with DPT, Measles, Polio vaccines (OPV and IPV), Hepatitis B, *Haemophilus influenzae* type B, and yellow fever vaccines and vitamin A supplementation.

REACTIONS AND SIDE EFFECTS

A local reaction is normal after BCG vaccination. The papule caused by the intradermal injection persists 15-30 minutes. Two or three weeks later a red nodule is observed and its dimensions increase for a further one or two weeks. In some cases a small abscess is formed which later develops into a small ulcer. The latter heals spontaneously without treatment in a few weeks. Three to six months after vaccination the ulcer heals completely and a small scar is formed. Enlargement of the axillary lymph-nodes may occasionally develop after vaccination but spontaneous regression usually occurs after a few months. In rare cases perforation and persistent suppuration can accompany the lymph-node enlargement and anti-tuberculous chemoprophylaxis may be indicated. Surgical excision is not recommended. Keloid and lupoid reactions may also occur at the site of injection.

CONTRAINDICATIONS AND WARNINGS

The vaccine is contraindicated in those individuals with cell-mediated immune deficiency including treatment with immunosuppressive drugs. Infants or children with keloid and lupoid reactions at the site of injection should not be revaccinated. Individuals known to be infected with HIV, either non-symptomatic or symptomatic, should NOT receive BCG vaccine.

STORAGE OF THE VACCINE

The vaccine should be stored and transported between +2°C and +8°C. It is even more stable if stored in temperatures as low as -20°C. The vaccine should be protected from the light. Once an ampoule has been opened, its contents should be used immediately. The diluent should not be frozen. Vaccine ampoules and diluents should be transported together.

SHELF LIFE

Not more than 36 months from the date of last satisfactory test for culturable particles, if stored in the dark at +2°C to +8°C.

PRESENTATION

The vaccine comes in boxes of 20 ampoules. The diluent is packed separately.

10-doses ampoule plus diluent
20-doses ampoule plus diluent

One ampoule of reconstituted vaccine contains 1 ml, corresponding to 10 doses for adults and children aged 12 months and over (0.1 ml) or 20 doses for infants under 12 months of age (0.05 ml).

**Manufactured
exclusively for**

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