## Name of the Product

**BCG VACCINE, FREEZE-DRIED powd. inj. 10 doses amp. + solv. 1 ml amp., x 20**

## Description:

Freeze-dried BCG Vaccine is a dried preparation containing live bacteria derived from a culture of the Bacillus Calmette and Guérin, known as BCG, intended for intradermal injection. The stabilizer is Sodium L-glutamate monohydrate. The vaccine does not contain preservatives.

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:

Each ampoule (10 Adult or 20 Infant doses) contains:

1. **Active substance**: Mycobacterium bovis *BCG* – 0.5 mg moist weight of BCG which corresponds to 0.15 mg dry weight and between $1.5 \times 10^6$ and $6.0 \times 10^6$ viable units.
2. **Stabilizer**: Sodium L-glutamate monohydrate – 3.0 mg per ampoule

Each single human dose (0.1 ml) contains:

1. **Active substance**: Mycobacterium bovis *BCG* – 0.05-mg moist weight of BCG that corresponds to $1.5 – 6.0 \times 10^5$ viable units.
2. **Stabilizer**: Sodium L-glutamate monohydrate – 0.3 mg per dose

## Form:

Powder and diluent for suspension for injection.

**Clinical part:**

**Indications:**

The vaccine is intended for specific prophylaxis of tuberculosis. As a part of national BCG programme, BCG vaccination is given to all healthy newborns, being administrated up to the day of leaving the maternity ward, not earlier than 48 hours after the birth. Those of the infants, who have not been immunized by various reasons, have to be immunized without prevaccination tuberculin tests, at the end of the second month at the latest. After that the infants are to be immunized only after tuberculin Mantoux test with 5 IU PPD tuberculin has been carried out. Only the infants, who have reacted negatively to this test, can be immunized.

The BCG revaccinations are given to all tuberculin-negative to 5 IU PPD tuberculin children of 6-7 (entering school), 10-11 and 16-17 years of age. The interval between the tuberculin test and the revaccination should not be more than 15 days.

**Administration:**

**The reconstituted vaccine should be given strictly intradermally.** The vaccination dose is 0.1 ml (0.05 ml) of the reconstituted vaccine.

Because of sensitivity to daylight, the vaccine suspension should be protected from the light. Any opened ampoule with re-suspended vaccine is to be used immediately. The residue of the suspension is to be discarded according to the rules for working with infectious material.

**Vaccination with BCG should be carried out by specially trained health personnel.**

**Contraindications:**

BCG vaccination and revaccination are given only to health individuals.

BCG is contraindicated in those persons with:

a. cell-mediated immune deficiency including treatment with immunosuppressive drugs;
b. non symptomatic HIV infected;
c. clinical form of AIDS;
d. keloid or lupoid reactions at the site of previous BCG vaccination;
e. adverse reactions after previous BCG vaccination (abscesses, suppurative lymphadenitis).
f. chronic dermatoses

**Interactions with another vaccines and medicines:**

BCG vaccine could be given at the same time with the following vaccines: DPT, DT, TT, Measles, Polio vaccines (OPV and IPV), Hepatitis B, Haemophilus influenzae type B and Yellow fever.

**Precautions:**

BCG vaccine must be injected strictly **intradermally.**

**Adverse reactions:**

In some rare cases a subcutaneous abscess could be formed (usually after incorrect vaccination technique is applied), long lasting ulcers (with diameter more than 10 mm in newborns and more than 20 mm in revaccinated persons), regional lymphadenitis , keloids etc.

**Pharmacological data:**

BCG vaccine confers protection against tuberculosis. It is given for vaccination and revaccination by the intradermal method.

**Pharmaceutical data:**

1. **Additional substances (per dose):**
   - 1.1 In lyophile:
     - 1.1.1. Sodium L-glutamate monohydrate (stabilizer) – 0.3 mg per dose
   - 1.2 In diluent:
     - 1.2.1. Sodium chloride – 0.9 mg
     - 1.2.2. Water for injection – 0.1 ml
2. **Physicochemical incompatibilities:**

   **Do not mix with other products.**
3. **Shelf life:**

Not more than thirty six months from the date of the last satisfactory test for culturable particles.

## 4. Storage of the vaccine:

BCG vaccine should be stored in a dry, dark place at a temperature between 2°C and 8°C. Transportation should also be at 2°C - 8°C.

The vaccine should be protected from the light. Once an ampoule has been opened, its content should be used immediately. The diluent should not be frozen. Vaccine ampoules and diluents should be transported together. During storage in refrigerator (2°C - 8°C) the product is stable until indicated date of expiration.

## 5. Presentation:

BCG is freeze-dried preparation in ampoules containing 10 doses (or 20 infant), sealed under vacuum. The final packing is a box with two blister-type carriers; each of them contains 10 ampoules with BCG vaccine.

The diluent is in ampoules, containing 1 ml Sodium Chloride 9 mg/ml. The final packing of diluent is also a box with two blister-type carriers, each of them contains 10 ampoules.

## 6. Precautions for use:

Special care is needed in opening the ampoule and reconstituting the vaccine gently with the sterile diluent provided. Prior to use, the bacterial mass should be shaken so that it falls to the bottom of the ampoule. As the ampoules are sealed under vacuum their top should be cut first. The square of plastic should be used to wrap around the ampoule, after which the neck can be broken off carefully to avoid escape of the dry powder. Sterile diluent is added and the content of the ampoule mixed by sucking up and down in the syringe to be used but using a long needle. Two to three minutes later a homogeneous slightly opalescent colorless suspension appears.

Specially trained health personnel should perform the immunization. The use of special tuberculin syringe and a sterile 26-gauge needle is to be used for each injection, so that exact dose can be administrated. A site 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. 0.1 ml of the reconstituted vaccine should be given intradermally. Attention is paid to strictly intradermal injection. Special care should be taken to avoid subcutaneous injection. Deep injection of the vaccine may increase the possibility of abscess formation.

**Possessor of the marketing authorization**:

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