

Manufacturer: Japan BCG Laboratory

Summary of Product Characteristic (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

FREEZE-DRIED GLUTAMATE BCG VACCINE (JAPAN) FOR INTRADERMAL USE

It is a live freeze-dried vaccine made from an attenuated strain of *Mycobacterium bovis*.

It is used for the prevention of tuberculosis. The vaccine fulfils WHO requirements for BCG vaccine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

(a) Live bacterial of Calmette and Guerin (as approximately 70% moist bacteria) 0.5mg/ampoule

(b) Sodium Glutamate (as a stabilizer) 2.0mg/ampoule

3. PHARMACEUTICAL FORM

Freeze-dried preparation

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is used for the prevention of tuberculosis.

4.2 Posology and method of administration

For children under one year 0.05 ml and for others 0.1ml of reconstituted vaccine is given intradermally. Special syringes allow administration of the exact dose. A sterile syringe and a sterile needle should be used for each injection. The skin should not be cleaned with antiseptic. Special care is needed in opening the ampoule so that the vaccine is not blown out. Because of sensitivity to ultraviolet light, the vaccine must be protected from sunlight. If not used immediately after reconstitution, the vaccine should be kept on ice to maintain its temperature between +2 and +8 degree C. Any opened container remaining at the end of a session (within six hours of reconstitution) 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 and +8 degree 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.

4.3 Contraindications

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

Do not give in pregnancy.

Immune deficiency

The vaccine is contraindicated in individuals with cell-mediated immune deficiency.

Individuals known to be infected with human immunodeficiency virus (HIV), either non-symptomatic or symptomatic, should NOT receive BCG vaccine.

4.4 Special warnings and precautions for use

N/A

4.5 Interaction with other medicinal products and other forms of interaction

N/A

4.6 Pregnancy and lactation

Do not give in pregnancy.

4.7 Effects on ability to drive and use machines

N/A

4.8 Undesirable effects

A local reaction is normal after BCG. 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, the nodule may persist and ulcerate.

Occasionally, enlargement of axillary lymph nodes may appear in 2-4 months following immunization. Very rarely, enlarged lymph nodes can suppurate. Inadvertent subcutaneous injection may produce abscess formation and may lead to scarring.

Anaphylaxis, including shock or anaphylaxis-like symptom, may appear. Although anaphylaxis is very rare, the subjects should be observed for an allergic reaction after BCG.

Very rarely, systemic disseminated BCG-infection, including osteitis or osteomyelitis, may appear, especially in persons with primary or secondary immunodeficiencies. Expert advice should be sought regarding the appropriate treatment regimen with selected anti-tuberculosis drugs for the management of systemic infections.

4.9 Overdose

N/A

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

N/A

5.2 Pharmacokinetic properties

N/A

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Glutamate

6.2 Incompatibilities

N/A

6.3 Shelf life

2 years

6.4 Special precautions for storage

BCG vaccine should be stored and transported between +2 and +8 degree C. it is even more stable if stored in temperatures as low as -20 degree C. The diluent should not be frozen. The vaccine should be protected from the light. Vaccine ampoules and diluents should be transported together. The expiry is specified on the BCG ampoule label.

6.5 Nature and contents of container

The vaccine comes in box of 100 ampoules each containing 0.5mg BCG (moisture weight).

The diluent in boxes of 100 ampoules each containing 1.0ml physiological saline accompanies all orders.

6.6 Special precautions for disposal and other handling

Reconstitution and Vaccination

File the neck part of the BCG ampoule with the file provided with the pack for cutting the ampoule. Wrap the filed site with the sheet provided with the pack to prevent the vaccine from blowing out of the ampoule as the interior of the ampoule is kept vacuum, and then snap to break off the ampoule at the filed site. With a syringe, add the whole amount of saline diluent into the BCG ampoule (A file is not needed to break off the diluent ampoule). Give a few gentle shakes to the ampoule to ensure homogeneity of the suspension. A homogeneous suspension in a concentration of 0.5mg per ml is now obtained. The vaccination site is about half way down the outer aspect of the upper arm. Do not vaccinate at the shoulder, nor revaccinate at a previously vaccinated site. Any volume of vaccine remaining in the container must be discarded.

Immunization Schedule

BCG should be given routinely to all infants at risk of early exposure to the disease. For maximum protection, this vaccine should be given as soon after birth as possible. It can be given at the same time as DTP, measles, polio (OPV and IPV), hepatitis B, Haemophilus influenzae type b, and yellow fever vaccines and vitamin A supplementation. Many countries still recommend not to give BCG within 4 weeks of another live vaccine.

7. MARKETING AUTHORISATION HOLDER (Drug Manufacturing License in Japan)

Japan BCG Laboratory

8. MARKETING AUTHORISATION NUMBER (Drug Manufacturing License in Japan)

13AZ001130

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

(Drug Manufacturing License in Japan)

Date of first authorisation: October 1952

Date of last renewal: January 1, 2012

10. DATE OF REVISION OF THE TEXT

December 2013