# SUMMARY PRODUCT CHARECTERISTICS

**Free Dried Glutamate BCG Vaccine (Japan) for intra-dermal use**

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| **DESCRIPTION** | It is a live freeze-dried vaccine made from an attenuated strain of *Mycobacterium bovis*, Tokyo172 substrain. It is used for the prevention of tuberculosis. The vaccine fulfills HWO requirements for BCG vaccine. |
| **THERAPEUTIC INDICATIONS** | It is used for the prevention of tuberculosis. |
| **DOSAGE & METHOD OF ADMINISTRATION** | For children under one year 0.05ml and for others 0.1ml of reconstituted vaccine is given intradermally.<br><br>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 the ice to maintain its temperature between +2 Degree Celsius and +8 degree Celsius. Any opened container remaining at the end of a session (within six hours of reconstitution) must be discarded.<br><br>The diluent supplied is specially designed for use with this vaccine. Only this diluents 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 incorrect diluents 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 Degree Celsius and + 8 Degree Celsius before reconstitution. If the vaccine vial monitor is present, it is removed on reconstitution.<br><br>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. |
| **CONTRAINDICATONS** | 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.<br>**Immune deficiency**<br>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. |
| **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.<br><br>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 scarring.<br><br>Shock or anaphylaxis 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 immune-deficiencies. Expert advice should be sought |

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| | regarding the appropriate treatment regimen with selected anti-tuberculosis drugs for the management of systemic infections. |
| **STORAGE OF VACCINES** | BCG vaccine should be stored and transported between +2 Degree Celsius and + 8 Degree Celsius. It is even more stable, if stored in temperatures as low as -20 Degree Celsius. The diluents should not be frozen. The vaccine should be protected from the light. Vaccine ampoule and diluents should be transported together.<br><br>Vaccine Vial Monitors (VVMs) are part of the label on all BCG supplied through JAPAN BCG LABORATORY. The colour dot, which appears on the label of the ampoule, is a VVM. This is a time-temperature sensitive do that provides an indication of the cumulative heat to which the ampoule has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.<br><br>The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the ampoule should be discarded.<br><br>The VVM does not extend life of a vaccine once it has been reconstituted. Even though the VVM indicates that the vaccine is acceptable, if it has been reconstituted, the vaccine should be used immediately on a maximum of 6 hours beyond reconstitution and then discarded. |
| **PRESENTATION** | The vaccine comes in boxes of 100 ampoules each containing 1,000 doses or 2,000 doses per box. The diluent in boxes of 100 ampoules accompanies all orders. |
| **MARKETING AUTHORIZATON HOLDER** | Manufacturer: Japan BCG Laboratory |
| **PRODUCT REGISTRATION NUMBER** | BHU-DRA/B02335 |