INSTRUCTION FOR USE
OF BCG VACCINE SSI
(FOR INTRADERMAL USE ONLY)

Description
BCG Vaccine is a live freeze-dried vaccine, made from an attenuated strain of Mycobacterium bovis (BCG), Danish Strain 1331. It is used for the prevention of tuberculosis, but does not ensure complete immunity. The Vaccine fulfills the Requirements for dried BCG vaccine (Requirements for Biological Substances No. 11) formulated by the WHO Expert Committee on Biological Standardization.

Declaration
1 ml of the reconstituted vaccine contains:
Mycobacterium bovis (BCG) Danish 1331                        0.75 mg
Sodium glutamate         3.75 mg
Magnesium                          125 microgram
Dipottassium phosphate         125 microgram
L-asparagine monohydrate              1 mg
Ferriammonium citrate        12,5 microgram
Glycerol (85%)                        18.4 mg
Citrin acid monohydrate           0.5 mg
Water for injection to                1 ml

Produced in Denmark by
Statens Serum Institut

Administration
FOR INTRADERMAL USE ONLY.
Dose for children below one year: 0.05 ml of the reconstituted vaccine and for others 0.1 ml. Use a sterile syringe and a sterile fine short needle for each injection (25 G or 26 G x 10 mm). The skin should not be cleaned with antiseptic. Jet injectors should not be used. The injection should be made slowly into the upper layer of skin. Injections made too deeply increase the risk of abcess formation.

The vaccine should be protected from light. Any suspended vaccine remaining at the end of an immunization session (maximum 4 hours) should be discarded.

Skin testing with tuberculin is not generally carried out before giving BCG, but when performed, those who are found to be positive reactors need to be immunized. A site frequently used for vaccination is the region over the distal insertion of the deltoid muscle (about halfway down the upper arm).

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 DPT, DT, TT, measles and polio vaccines (OPV and IPV).

Side 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 a 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. Inadvertent subcutaneous injection produces abcess formation and may lead to ugly retracted scars.

Precautions
BCG vaccination is not recommended during pregnancy and in presence of acute or chronic disease especially virus infection nor in severe extended skin disease.
Contraindications
The vaccine is contraindicated in those with cell-mediated immune deficiency including treatment with immunosuppressive drugs.

Human immunodeficiency virus (HIV) infected persons: 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.

Storage
BCG Vaccine deteriorates when exposed even for short periods to direct sunlight and diffuse daylight (also indoors). The freeze-dried vaccine gradually loses its potency. During storage in a refrigerator (between +2°C - +8°C) the vaccine is stable. However, at 37°C a significant loss of potency will accrue within a few weeks. The deleterious effect of exposing the vaccine to high temperature is cumulative. The freeze-dried vaccine should be kept continuously between +2°C - +8°C. The diluent should not be frozen.

HARUS DENGAN RESEP DOKTER

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