Package leaflet: Information for the user

BCG Vaccine AJV POWDER and SOLVENT for suspension for injection
(FOR INTRADERMAL USE ONLY)

Description
BCG Vaccine AJV 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 fulfils 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 strain 1331 2.0 x 10^6 – 8.0 x 10^6 CFU (Colony Forming Units)	0.75 mg
Sodium glutamate	3.75 mg
Magnesium sulphate	125 microg.
Dipotassium phosphate	125 microg.
L-asparagine monohydrate	1 mg
Ferric ammonium citrate	12.5 microg.
Glycerol (85%)	18.4 mg
Citric acid monohydrate	0.5 mg
Water for injections	to 1 ml

Produced in Denmark by
AJ Vaccines A/S, 5, Artillerivej, 2300 Copenhagen S, Denmark

Administration

FOR INTRADERMAL USE ONLY.

Reconstitution:
Only the solvent provided with BCG Vaccine AJV should be used for reconstitution.
The rubber stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, it must be allowed to evaporate before the stopper is penetrated with the syringe needle.
The vaccine should be visually inspected both before and after reconstitution for any foreign particulate matter prior to the administration.
Using a syringe fitted with a long needle, transfer to the vial the volume of solvent given on the label. Carefully invert the vial a few times to resuspend the lyophilised BCG completely.

DO NOT SHAKE. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose. When drawn up into the syringe the vaccine suspension should appear homogeneous, slightly opaque and colourless.

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. A site frequently used for vaccination is the region over the distal insertion of the deltoid muscle (about halfway down the upper arm). Injections made too deeply increase the risk of abscess formation.

The vaccine should be protected from light. Any unused portion should be disposed by incineration or by treatment with disinfectant. Use within 4 hours after reconstitution.

Skin testing with tuberculin is not generally carried out before giving BCG, but when performed, those who are found to be have a positive reaction do not need to be immunized.

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

Other vaccines administered at the same time as BCG Vaccine AJV should not be injected into the same arm.
If not administered simultaneously, an interval of not less than 4 weeks should be left between the administrations of any two live vaccines.
Further vaccinations in the arm used for the BCG vaccination must not be given for 3 months due to risk of regional lymphadenitis.

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 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. Inadvertent subcutaneous injection produces abscess formation and may lead to ugly retracted scars.

Suppurative lymphadenitis may occur. This is a benign condition which heals spontaneously, although often only slowly.

Undesirable effects of the vaccine include the following:

	Uncommon (≥1/1000 to <1/100)	Rare (≥1/10000 to <1/1000)
Blood and lymphatic system disorders	• Enlargement of lymph nodes > 1 cm	-
Nervous system disorders	• Headache	-
Musculoskeletal and connective tissue disorders	-	• Osteitis
Infections and infestations	• Suppurative lymphadenitis	• Osteomyelitis • Injection site abscess
General disorders and administration site conditions	• Fever • Injection site ulceration • Injection site discharge	-
Immune system disorders	-	• Anaphylactic reaction • Allergic reaction

If inadvertent systemic or persistent local infection with the BCG vaccine occurs, expert advice should be sought regarding the appropriate treatment regimen.
Treatment with recommended antituberculous drugs include rifampicin, ethambutol, streptomycin and isoniazid. However, isoniazid is considered to be of intermediate susceptibility. BCG Danish strain 1331 is resistant to pyrazinamide.

Contraindications
BCG Vaccine AJV must not be administered to persons known to be hypersensitive to any component of the vaccine.
Vaccination should be postponed in persons suffering from acute severe febrile illness or with generalised infected skin conditions. Eczema is not a contraindication, but the site of vaccination should be lesion-free.
The BCG vaccine should not be given to persons with the following:

- Children and adults with or suspected to have immune deficiency including treatment with immunosuppressive drugs or other immunosuppressive treatment including radiotherapy. This also includes infants exposed to immunosuppressive treatment in utero or via breastfeeding, for as long as a postnatal influence of the immune status of the infant remains possible (e.g. maternal treatment with TNF-α antagonists).Persons with malignant conditions (e.g. lymphoma, leukemia, Hodgkin's disease or other tumours of the reticulo-endothelial system).
- Primary or secondary immunodeficiency, including HIV infection and infants born to HIV-positive mothers, even if they show no symptoms of HIV infection
- Persons whose immune system is in question

The effect of BCG vaccination may be exaggerated in these persons, and a generalized BCG infection is possible.

BCG Vaccine AJV must not be given to patients receiving anti-tuberculosis drugs.

Storage
BCG Vaccine AJV must always be stored in a refrigerator (+2°C to +8°C) in the original package in order to protect from light. The vaccine deteriorates when exposed to direct sunlight and diffuse daylight (also indoors), even for shorter periods.

The solvent, can be stored outside the refrigerator. Do not freeze.