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Manufactured Products

World Class Products. World Class Care.



DESCRIPTION

TUBERVAC (Bacillus Calmette-Guerin Vaccine I.P.) is a live freeze-dried vaccine derived from attenuated strain of mycobacterium bovis. TUBERVAC used for the prevention of tuberculosis. The vaccine meets the requirements of W.H.O. and I.P. when tested by the methods outlined in W.H.O., TRS. 745 (1987), 777 (1988) and I.P.

COMPOSITION

Each 1ml contains between :

1 x10⁶ and 33 x 10⁶ Colony Forming Units (C.F.U.)

Diluent : Sodium Chloride Injection I.P.

Dose : 0.05 ml for children under one month of age.

0.1 ml for children over one month of age and adults.

RECONSTITUTION

TUBERVAC 10/20 dose vial should be reconstituted by adding the entire contents of Sodium Chloride Injection I.P. supplied. Carefully invert the vial a few times to resuspend freeze dried BCG. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose. The resulting suspension should be homogenous, slightly opaque and colourless. Reconstitute only with diluent provided by manufacturer. Using an incorrect diluent may result in damage to the vaccine and/or serious reactions to those receiving the vaccine. Use immediately after reconstitution. If the vaccine is not used immediately then it should be stored in the dark between 2° and 8°C for no longer than 6 hours.

Any opened vial remaining at the end of a vaccination session (within six hours of reconstitution) must be discarded.

The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.

DOSAGE AND ADMINISTRATION

This vaccine is intended to be injected strictly via the intradermal route.

Universal Immunization Programme (UIP) of Government of India recommends 0.05 ml for children under one month of age and 0.1 ml for children over one month of age and adults of reconstituted vaccine given intradermally. The vaccine should be preferably given with a tuberculin syringe or 25G/26G sterile needle and syringe.

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.

INTRADERMAL INJECTION TECHNIQUE

The skin is stretched between thumb and forefinger and sterile needle (25 G or 26 G) inserted bevel upwards for about 2mm into superficial layers of the dermis (almost parallel with the surface). Raised blanched bleb showing tips of hair follicles is a sign of correct injection. 7mm bleb = 0.1ml injection. The site of injection is at insertion of the deltoid muscle into the humerus. Sites higher on the arm are likely to lead to keloid formation.

INDICATIONS AND IMMUNIZATION SCHEDULE

TUBERVAC should be given routinely to all infants at risk of early exposure to tuberculosis. In India the national policy is to administer BCG very early in infancy at birth. BCG administered early in life provides high level of protection particularly against severe forms of childhood tuberculosis and tubercular meningitis. In countries with low prevalence of tuberculosis, BCG vaccination should be restricted to high risk groups such as hospital personnel and tuberculin negative contacts of known cases of tuberculosis. The vaccine can be given simultaneously with DTP, DT, TT, Measles., Polio and Hepatitis B vaccines, but at a separate site.

CONTRAINDICATIONS AND PRECAUTIONS

TUBERVAC is contraindicated in hypogamma-globulinemia, congenital immunodeficiency, sarcoidosis, leukaemia, generalised malignancy, HIV infections or any other disorder in which natural immune response is altered, as also those on immunosuppressive therapy, corticosteroids, radiotherapy. In chronic eczema or other dermatological disease, the vaccine can be given in a healthy area of the skin.

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

SPECIAL CASE OF CHILDREN BORN TO HIV SEROPOSITIVE MOTHERS.

The obligatory passage of maternal antibodies of the IgG type through the placenta makes it impossible to interpret the serology of the child until the age of about 9-10 months (persistence of the maternal antibodies has been detected up to 14 months).

It is therefore necessary to wait until the child has been found to be seronegative, as determined by immuno-transfer (Western Blot) with the support, if necessary, of techniques for detecting the viral genome, before confirming that the child is not infected.

If the child is infected, BCG vaccine is contraindicated irrespective of the child's condition, given the potential risk of development of "BCG-itis" in the vaccinated child. The advice of a specialized medical team is required.

DRUG INTERACTIONS AND OTHER INTERACTIONS

TUBERVAC may be routinely given to any child exposed early to the risk of contact with the disease (tuberculosis). In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor.

There is no indication to vaccinate women during pregnancy.

Breast feeding can continue despite vaccination with BCG vaccine.

As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's advice before using a medicinal product.

SIDE EFFECTS

A local reaction is normal. Following BCG vaccination, 2 to 3 weeks later a papule develops at the site of vaccination and increases slowly in size to a diameter of 4-8 mm in 5 weeks. It then subsides or breaks into a shallow ulcer covered with a crust. Healing occurs spontaneously in 6-12 weeks leaving a permanent, tiny round scar 2-10 mm in diameter. In rare cases an abscess may appear at the point of injection, or satellite adenitis, leading in exceptional cases to suppuration. Exceptional cases of lupus vulgaris at the injection site have been reported. Inadvertent subcutaneous injection produces abscess formation and may lead to ugly scars. A risk of generalised reaction to BCG exists in immunodepressed individuals vaccinated with BCG or living in contact with a vaccinated individual.

STORAGE

TUBERVAC should be stored in dark between 2° and 8°C. Protect from light. The diluent should not be frozen, but should be kept cool.

SHELF LIFE

24 months from the date of last satisfactory potency test if stored in a dark place at recommended temperature.

PRESENTATION

10/20 doses vial plus diluent (1 ml).

10 x 10/20 doses vial plus diluent (1 ml).

50 x 10/20 doses vial plus diluent (1 ml).



