

BCG VACCINE

(Freeze-Dried)

DESCRIPTION

BCG Vaccine is a live freeze-dried vaccine derived from attenuated strain of *Mycobacterium bovis* (Bacillus Calmette-Guérin Moscow strain 361-1) used for the prevention of tuberculosis. The vaccine is a white and crystalline in appearance. It contains sodium phosphate buffer, gelatin, and other stabilizing agents. The vaccine meets the requirements of WHO when tested by the methods outlined in WHO Technical Report Series No. 723 (2013).

COMPOSITION

Live attenuated BCG Vaccine (Bacillus Calmette-Guérin Strain)

Each 0.1 ml contains between 2×10^7 and 8×10^7 C.F.U.

Reconstituted with Sodium Chloride Injection

Dose: 0.05 ml. Intradermal for infants under one year old.

: 0.1 ml. Intradermal for children over one year of age and adult.

RECONSTITUTION

Tap the vaccine vial gently so as to get the white and crystalline vaccine powder at the bottom of the vial. BCG vaccine vial of 0.1 ml (0.05 ml) for infants under one year old (710 doses) (0.1 ml) for children over one year of age and adult to be reconstituted by adding the entire content of the supplied container of diluent (Sodium Chloride Injection). Carefully invert the vial a few times to re-suspend freeze dried BCG. Gently swirl the vial of re-suspended vaccine before drawing up each subsequent dose. The resulting suspension should be homogeneous, slightly opaque and colourless. The reconstituted suspension may occasionally show clumping, which is normal characteristic of *Mycobacterium bovis*. Avoid vigorous shaking which may enhance aggregate clump formation. Reconstitute only with diluent provided by manufacturer. Using an injector, children 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 must be stored in the dark at 2-8 °C for no longer than 6 hours (1 minimum six hours).

Any opened vial remaining at the end of a vaccination session (within six hours of reconstitution) must be discarded. The vaccine vial monitor for this type of vaccine is attached to the vial cap and should be discarded when the vaccine is being reconstituted.

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.

DOSEAGE AND ADMINISTRATION:

The vaccine is intended to be injected strictly via the intradermal route, avoiding the subcutaneous route.

The vaccination dose is 0.05 ml for children under one year of age including the newborn and 0.1 ml for children over one year of age and adult of the reconstituted vaccine given intradermally. The skin should not be cleaned with antiseptic. The vaccine should be preferably given with a tuberculin syringe or 25 G 26 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 reactions 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 2 mm 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. 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

BCG vaccine should be given routinely to all infants at risk of early exposure to tuberculosis. This vaccine should be given soon after the child is born. 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, Tetanus, Polio, Hepatitis B, *Hemophilus influenzae* type b, yellow fever vaccines and vitamin A supplementation, but at a separate site.

CONTRAINDICATIONS AND PRECAUTIONS

BCG vaccine is contraindicated in hypogammaglobulinemia, congenital immunodeficiency, sarcoidosis, leishmaniasis, generalized 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 upward reactions may also occur at the site of injection and such children should not be re-vaccinated.

INFORMATION OF ANTITUBERCULOSIS DRUGS

The Minimum Inhibitory Concentration (MIC) towards the *Mycobacterium bovis* BCG Moscow strain 361-1 is indicated in below mentioned table.

Drug	Minimum Inhibitory Concentration (MIC)
Isoniazid	0.5 µg/ml
Streptomycin	1.0 µg/ml
Rifampicin	1.0 µg/ml
Ethambutol	5.0 µg/ml

In case of systemic or persistent local infection with BCG vaccine occurs, expert advice should be taken for the necessary treatment. BCG Moscow strain 361-1 is resistant to pyrazinamide.

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 before determining 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. In the case of a child born to an HIV positive mother, the child is infected BCG vaccine is contraindicated irrespective of the child's condition, given the guidelines of the WHO (2013). The vaccine is contraindicated in babies who do not develop BCG scar as advocated in the guidelines of the WHO (2013).

IMMUNODEFICIENCY

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.

DRUG INTERACTIONS AND OTHER INTERACTIONS

The BCG vaccine 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 suppurative. Exceptional cases of pig's warts at the injection point have been reported. Indurated, subcutaneous injection products abscess formation and may lead to ugly scars. A risk generalised reaction to BCG exists in immunodepressed individuals vaccinated with BCG or living in contact with a vaccinated individual.

STORAGE

BCG vaccine (Freeze-dried) should be stored in dark, between 2° to 8 °C. It is even more stable if stored in temperatures as low as -20 °C. Protect from light. The vials 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

20 / 10 doses vial plus diluent (1 ml)

THE VACCINE VIAL MONITOR (OPTIONAL)

- ✓ Inner square lighter than outer circle. If the expiry date has not passed, USE the vaccine.
- ✓ At a later time, inner square still lighter than outer circle.
- ✓ Discard point: Inner square darker colour of outer circle.
- ✗ DO NOT use the vaccine.
- ✗ Beyond the discard point, inner square is darker than outer ring.
- ✗ DO NOT use the vaccine.

Vaccine Vial Monitors (VVMs) are on the cap of BCG Vaccine supplied through Serum Institute of India Pvt. Ltd. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level. The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively as long as the colour of the 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 vial should be discarded.



Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsat, Pune 411028, INDIA
Protection from birth onwards

VACUNA BCG

(Liofilizada)

DESCRIPCION

La vacuna de BCG es una vacuna viva liofilizada derivada de la cepa atenuada de *Mycobacterium bovis* (Bacillus Calmette y Guérin, cepa Moscow 361-1) usada en la prevención de la tuberculosis. La vacuna liofilizada es un aspecto blanco/cristalino. Contiene glutarato de sodio como estabilizante. La vacuna cumple con los requisitos de la O.M.S., cuando se la comprueba según los métodos establecidos en la O.M.S., TBC: 979 (2013).

COMPOSICION

Vacuna BCG viva, atenuada (Cepa Bacillus Calmette Guérin)

Cada 0.1 ml contiene entre 2×10^7 y 8×10^7 C.F.U.

Reconstituir con Inyección de Cloruro de Sodio

Dosis: 0.05 ml. Intradérmica para niños con edad de más de un año de edad.

: 0.1 ml. Intradérmica para niños con edad de más de un año de edad.

RECONSTITUCION

Sacudir el frasco de la vacuna suavemente para obtener un polvo cristalino y blanco de la vacuna en el fondo del frasco. BCG frasco de vacuna de 0.1 ml (0.05 ml) para los niños mayores de un año de edad (10 dosis) (0.1 ml) para niños mayores de un año de edad y un adulto para reconstituirse añadiendo todo el contenido del envase de diluyente suministrado (inyección de cloruro de sodio). Invertir el frasco de la vacuna con cuidado unas veces para re-suspender la BCG liofilizada. Agitar suavemente el frasco de la vacuna resuspendida antes de aspirar cada dosis subsiguiente. La suspensión resultante debe ser homogénea, un poco opaca y decorada. La suspensión reconstituida puede ocasionalmente tener masas, que es una característica de *Mycobacterium bovis*. Evitar agitar vigorosamente que puede aumentar y agravar la formación de masas. Reconstituir únicamente con el diluyente provisto por el fabricante. El uso de un diluyente incorrecto puede resultar en perjuicio a la vacuna y / o reacciones serias en personas que reciben la vacuna. Usar inmediatamente después de la reconstitución. En el caso de no utilizar la vacuna inmediatamente, se la debe conservar al abrigo de la luz entre 2-8 °C por no más de 6 horas (1 sesión de vacunación).

Cualquier frasco abierto solamente al fin de una sesión de vacunación (dentro de seis horas de su reconstitución) debe ser descartado. El sellado de control del frasco de este tipo de vacuna se encuentra adherido a la tapa y debe descartarse al reconstituir la vacuna.

El diluyente y la vacuna reconstituida deben examinarse visualmente para averiguar cualquier materia particulada y / o variación de aspectos físicos antes de la administración. En caso de que se observa uno u otro, descartar el diluyente o la vacuna reconstituida.

POSOLOGIA Y VIA DE ADMINISTRACION

La vacuna está destinada para la inyección estrictamente por vía intradérmica evitando la inyección por vía subcutánea.

La dosis vacunal es de 0.05 ml para niños con edad de menos de 1 año incluyendo los recién nacidos y 0.1 ml para niños mayores de un año de edad y los adultos de la vacuna reconstituida, administrada intradérmicamente. No se debe limpiar la piel con antiséptico. Se debe administrar la vacuna liofilizada no se reconstituye con agua y peróxido de hidrógeno de 25 G / 26 G. Hematoma no se reconstituye con agua y peróxido de hidrógeno de 25 G / 26 G. Se debe demostrar a los niños con los resultados positivos que no se reconstituyen.

METODO DE INYECCION INTRADERMICA

Estirar la piel entre el pulgar y el índice e introducir la aguja estéril (25 G o 26 G) bisel hacia arriba, penetrando 2 mm en las capas superficiales de la dermis (casi paralela a la superficie). La administración correcta de esta inyección debe producir una mancha elevada en la piel en los puntos de los folículos visibles. El punto de inyección es en la región de la inserción del músculo deltoides en el humero. Un punto de inyección más arriba en el brazo puede llevar a la formación de queloides.

INDICACIONES Y ESQUEMA DE VACUNACION

La vacuna BCG debe ser administrada rutinariamente a todos los niños con riesgo de exposición a la tuberculosis. Esta vacuna debe ser administrada a los recién nacidos como antes. La temprana administración de BCG resulta en un alto nivel de protección, especialmente contra las formas severas de tuberculosis de infancia y la meningitis tuberculosa. En países con baja prevalencia de tuberculosis, la vacuna BCG debe ser administrada únicamente a grupos de alto riesgo tales como el personal en los hospitales y personas con reacciones negativas tuberculinas que han venido en contacto con casos establecidos de tuberculosis. La vacuna se puede administrar simultáneamente con DTP, DT, TT, el sarampión, la poliomielitis, la hepatitis B, *Hemophilus influenzae* tipo b, la fiebre amarilla y suplementos de vitamina A, pero en un lugar separado.

CONTRAINDICACIONES Y PRECAUCIONES

La vacuna BCG está contraindicada en hipogammaglobulinemia, déficits inmunitarios congénitos, sarcoidosis, leishmaniasis generalizada, infecciones VIH o cualquier otra condición en que la inmunidad natural se altera, así como en los sujetos recibiendo la terapia inmunosupresiva, corticosteroides, radioterapia. En condiciones de eczema crónica o otras enfermedades dermatológicas, la vacuna puede ser administrada en la parte sana de la piel. Pueden ocurrir reacciones queloides y lipoides en el punto de la inyección y tales niños no deben ser re-vacunados.

INFORMACION DE MEDICAMENTOS ANTITUBERCULOSIS

La concentración mínima inhibitoria (MIC) hacia el *Mycobacterium bovis* BCG Moscow cepa 361-1 que se indica en la tabla a continuación se muestra.

Drugs	Concentration Minimum Inhibitory (MIC)
Isoniazid	0.5 µg/ml
Streptomycin	1.0 µg/ml
Rifampicin	1.0 µg/ml
Ethambutol	5.0 µg/ml