PATIENT INFORMATION LEAFLET

BCG VACCINE, FREEZE-DRIED

vaccine against tuberculosis (live attenuated bacilli of M. bovis, BCG strain)

1 vial of the reconstituted vaccine contains:
1 mg/1 mL live bacteria Bacillus Calmette-Guérin
(Mycobacterium bovis BCG)
(1.6–16.0 x 10^6 CFU/mL)

20 doses (0.05 mL per dose) for newborns and infants under 12 months of age
of
10 doses (0.1 mL per dose) for adults and children over 12 months of age
powder and solvent for suspension for injection

1. WHAT BCG VACCINE IS AND WHAT IT IS USED FOR

BCG vaccine is a freeze-dried vaccine consisting of live, attenuated Mycobacterium bovis bacilli, strain Bacillus Calmette-Guérin.

Vaccination with BCG vaccine elicits a cell-mediated immune response that confers a variable degree of protection against tuberculosis (protective effect of vaccination is 40-70%). Numerous BCG vaccine efficacy studies in children show that this vaccine does not prevent the infection with M. tuberculosis, but when applied immediately at birth it provides a significant protection of infants and little children against tuberculous meningitis and disseminated forms of tuberculosis.

BCG vaccination does not prevent reactivation of latent pulmonary tuberculosis. The vaccine-induced protection decreases over time.

BCG vaccine is intended for active immunisation of all newborns and children at a high risk of tuberculosis to prevent severe clinical forms of tuberculosis (tuberculous meningitis and disseminated tuberculosis), and for active immunisation of adults at a high risk of developing tuberculosis.

BCG vaccine is given to newborns on being discharged from the maternity hospital. Children who have not received BCG vaccine until two months of age must be vaccinated in competent health institutions until they reach 12 months of age.

BCG vaccine immunisation schedule is developed in compliance with the national immunisation programme.

Exceptionally, BCG vaccine can be administered to personnel in maternity hospitals, and paediatric institutions, as well as to other healthcare workers with a high risk of exposure to tuberculosis, if they have not received the vaccine up to that moment in the primary vaccination. Also, BCG vaccine can be given to children at a high risk of tuberculosis who were not vaccinated in the primary vaccination, if members of their family have had tuberculosis or are coming from a country with a high prevalence of tuberculosis, or at the request of parents, if they are coming from a country in which BCG vaccination is not conducted.

BCG vaccine should be given only to persons who have not received BCG vaccine and who have not been infected with Mycobacterium tuberculosis or who have a negative tuberculin reaction. BCG vaccination has no value in the treatment of persons with tuberculosis (infection with Mycobacterium tuberculosis).

2. BEFORE YOU RECEIVE BCG VACCINE

Do not use BCG VACCINE:

Contraindications to active BCG vaccine immunisation are:
- serious allergic reactions (e.g. anaphylaxis) to certain components of the vaccine or manifested during administration of the previous vaccine dose;
- known severe immunodeficiency, such as haematological or solid tumours, chemotherapy, radiotherapy, or long immunosuppressive therapy (use of prednisone or an equivalent corticosteroid for ≥ 2 weeks in the dose ≥ 20 mg/day is considered a sufficient immunosuppressive dose that can lead to severe immunodeficiency); then congenital immunodeficiency (e.g. chronic granulomatous disease or interferon gamma receptor deficiency), as well as seriously immunocompromised persons with HIV infection (in those persons BCG vaccination increases the risk of a generalised BCG infection);
- pregnancy (although no harmful effects to the fetus have been associated with the vaccine, BCG vaccination should be postponed for the period after the delivery);
- active tuberculosis (BCG vaccine should not be given to patients who are receiving anti-tuberculosis medications).

In case of a moderate to severe acute disease with or without fever, the administration of BCG vaccine should be postponed until the condition stabilises.

Preterm babies or newborns with severe complications at birth (intracranial haemorrhage, icterus gravis neonatorum, pern phíphus gravis neonatorum, etc.) are to be vaccinated as soon as their condition is normalised.

The vaccination should be postponed in persons with generalised infected skin conditions or burns. Eczema is not a contraindication, but the vaccine site must be lesion free.

Take special care with BCG VACCINE:
- In case of a change in the physical appearance of the prepared BCG vaccine (colour change, presence of visible particles, not easily removable precipitate) the vaccine must not be applied.
- Prior to BCG administration, an assessment of the vaccinee’s health status needs to be done to determine if certain contraindications to the application of BCG vaccine are present, or if there is a need to postpone immunisation until the status is clarified completely, i.e. until the status is stable.
- Prior to the vaccination, all relevant information on the vaccinee’s medical status need to be collected so as to take appropriate precautions (if necessary).
- Prior to the immunisation, it is necessary to have a detailed medical history of the previous hypersensitive reactions for each patient. In patients allergic to certain medicines (or food) or those prone to hypersensitive reactions after the contact with various agents, special precautions need to be taken during the BCG vaccine application.
- The health institution in which the vaccination takes place must provide suitable medical treatment in case of an anaphylactic shock. All vaccinees should be under the doctor’s supervision for at least 30 minutes after the vaccine administration.
- Special caution is required during BCG vaccine administration in newborns and children with medical history suggestive of congenital immunodeficiency or any risk factors for HIV infection. Newborns who have potentially been exposed to HIV perinatally must not be given BCG vaccine until they have been confirmed not to be infected with HIV.
- Tuberculic positive persons do not require the vaccine. Administration of
- BCG vaccine to such persons may result in a severe local reaction.
- BCG vaccine must not be injected intravascularly and intramuscularly. When administering the vaccine, the needle should not enter a blood vessel or the surrounding muscle tissue. BCG vaccine must not be given by a too deep subcutaneous injection, due to the possibility of lymphadenitis and abscess development.

BCG vaccine should be injected strictly intradermally.

Using other medicines

BCG vaccine may be given concurrently with other inactivated live vaccines, but at different injection sites using separate syringes.

Other vaccines to be given at the same time as BCG vaccine or during the next three months should not be given into the same (left) arm because of the risk of regional lymphadenitis.

BCG vaccine must not be mixed with other vaccines and/or other medicines in the same syringe.

Studies have shown that concurrent application of BCG vaccine and hepatitis B vaccine at birth does not have any influence on immunogenecity and safety of either vaccine. However, since the application of one live vaccine may interfere with the efficacy of another, BCG vaccine is not recommended to be administered in the period of 4 (four) weeks after the administration of any live vaccine.

Using BCG VACCINE with food and drink

Not applicable.

Pregnancy and breast-feeding

Preliminary trials of BCG vaccine reproductive toxicity have not been conducted and it is not known whether this vaccine (when administered to a pregnant woman) may show teratogenic effects and cause fetal harm. Therefore, BCG vaccination of pregnant women should be delayed until after delivery.

It is not known whether BCG vaccine is excreted in mother’s milk. Because live vaccines may be excreted in human milk, special caution should be exercised when BCG vaccine is administered to a nursing woman.

Driving and using machines

BCG vaccine does not affect the psychophysical capacities.

Important information about some of the ingredients of BCG VACCINE

In case of a known hypersensitivity (allergy) to any of the components of the vaccine, including excipients (gelatin, sucrose, sodium chloride), the vaccine must not be used.
3. HOW TO USE BCG VACCINE

Posology:
The dose of BCG vaccine for newborns and infants under 12 months of age is 0.05 mL of the reconstituted vaccine and contains 0.05 mg of M. bovis BCG (0.8-8.0 x 10^8 CFU).
The dose of BCG vaccine for children over 12 months of age and adults is 0.1 mL of the reconstituted vaccine and contains 0.1 mg of M. bovis BCG (1.6-16.0 x 10^8 CFU).
The vaccine is to be reconstituted before use. Original solvent, delivered with the particular batch of the vaccine, should always be used. If alcohol is applied to swab the rubber stopper, it should be allowed to evaporate. The vaccine is to be reconstituted by transferring the solvent (1 mL) to the vial containing the freeze-dried vaccine using a sterile syringe fitted with a needle (the rubber stopper is not to be removed). To suspend the vaccine, the vial should be gently turned upside down a few times. Making of air bubbles should be avoided, due to precise dosing of the suspension. The vaccine should be homogenous and slightly opaque. Any unused reconstituted vaccine in a multi-dose presentation should be discarded after max. 4 hours.

Method of administration:
BCG vaccine should be injected intradermally in the deltoid muscle area, at the junction of the external and internal side of the left upper arm. Use a sterile syringe of 1 mL subgraduated into hundredths of mL (1/100 mL) fitted with a needle for intradermal use.
BCG vaccine should be administered by specially trained medical personnel under the supervision of an experienced doctor. The vial should be gently swirled before drawing up each subsequent dose. Slightly more than one dose should be drawn up, and any air bubbles and extra vaccine should be removed. Antiseptics should be allowed to evaporate completely from the skin before the injection is made. The skin should be stretched between the thumb and index finger. The needle should be almost parallel with the skin surface and the bevel of the needle facing upwards. The needle should be inserted slowly, approximately 2 mm into the superficial layer of the dermis. The needle should be visible through the epidermis during insertion. The vaccine is to be injected slowly. A raised, blanching blotch sized 8 to 10 mm is a sign of correct BCG vaccine injection. The rete at the injection site soon disappears and transient redness develops. Three weeks after, a specific reddish cell infiltrate appears which later colliquates and ulcerates. Over the next 2-5 months, it heals spontaneously leaving a scar 2-10 mm in diameter. The scar becomes stable, discoloured, and most often slightly retracted.

Note:
The recommended dosage for age should not be exceeded, as this increases the risk of more extensive local reactions and other undesired complications. A new disposable syringe and intradermal needle should be used for each vaccinee.
Keep the vaccine at room temperature for a short while prior to the injection.

If you use more BCG VACCINE than you should
The recommended dosage for age should not be exceeded, as this increases the risk of more extensive local reactions and other undesired complications.

If you forget to take BCG VACCINE
No data.

Effects when treatment with BCG VACCINE is stopped
Not applicable.

4. POSSIBLE SIDE EFFECTS

The expected reaction to a successful BCG vaccination includes redness at the injection site, and after three weeks an infiltrate that ulcerates and heals spontaneously over 2 to 5 months, leaving a scar of 2-10 mm in diameter. It may also include enlargement of regional lymph nodes up to 1 cm.
A strong response to BCG vaccine may occur due to spreading of the infiltrate from the formed ulcer and forming of a larger post-vaccination scar. The reason for this could be subcutaneous vaccination (instead of intradermal) or a larger dose. The ulcer should be encouraged to dry and wearing clothes made of crude material should be avoided.
Adverse reactions are given as per their frequency:
very common > 1/10
common > 1/100 and < 1/10
uncommon > 1/1000 and < 1/100
rare > 1/10,000 and < 1/1,000
very rare < 1/10,000
individual cases.
The estimation of adverse reactions frequency is based on WHO data.

5. HOW TO STORE BCG VACCINE, FREEZE-DRIED

Shelf-life
Shelf-life of BCG VACCINE, FREEZE-DRIED in the original packaging is 12 months. Shelf-life of the vaccine after reconstitution is 4 h.
Do not use the vaccine after the expiration of the date stated on the outer packaging.

Storing
Store the vaccine in the original packaging in a refrigerator at 2°C to 8°C, protected from light.
Store the reconstituted vaccine for maximum 4 hours in a refrigerator at 2°C to 8°C, protected from light.
Do not freeze.

6. FURTHER INFORMATION

What BCG VACCINE, FREEZE DRIED contains
Active substance:
1 vial of the reconstituted vaccine contains 1 mg/1 mL of Mycobacterium bovis strain Bacillus Calmette-Guerin (1.6-16.0 x 10^6 CFU/mL) which corresponds to 20 doses of 0.05 mL for newborn and infants under 12 months of age or 10 doses of 0.1 mL for adults and children over 12 months of age.
Other ingredients are:
- Medium for freeze-drying: Gelatin
- Solvent: Sucrose
- Sodium chloride
- Water for injections

What BCG VACCINE, FREEZE DRIED looks like and content of the pack
Powder for suspension is packed in a vial of amber glass Type I (Ph. Eur.) sealed with rubber stopper Type I (Ph. Eur.).
Solvent is packed in an ampoule of clear glass Type I (Ph. Eur.).
Package of 5 vials with freeze-dried vaccine and 5 ampkules of solvent together with the Patient Information Leaflet are packed in a PVC blister inside a cardboard box.

Marketing Authorisation Holder and Manufacturer
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Dispensing regime:
The medicine can be dispensed in a health institution.

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