BCG VACCINE SSI
Vaccinum tuberculosis (BCG) cryodesiccatum

FOR INTRADERMAL USE

Description
BCG, SSI is a freeze-dried preparation of live bacteria derived from a culture of the bacillus of Calmette and Guérin (Mycobacterium bovis BCG) whose capacity to protect against tuberculosis has been established.

The vaccine should be reconstituted with Diluted Sauton SSI before use.

1 ml reconstituted vaccine contains 2 to 8 million Colony Forming Units of Mycobacterium bovis BCG, Danish strain 1331.

Other ingredients: Sodium glutamate, Magnesium sulphate heptahydrate, Dipotassium phosphate, L-asparagine monohydrate, Feric ammonium citrate, Citron (8%), Citric acid monohydrate, Water for injections.

The vaccine is manufactured without the use of ingredients of human or animal origin. The vaccine does not contain preservatives. The container closure does not contain latex (natural rubber).

Indications
Active immunisation of infants, children, and adults against tuberculosis. BCG-vaccines do not ensure complete immunity.

Contraindications
Known hypersensitivity to any component of the vaccine. Systemic treatment with corticosteroids or treatment with immuno-suppressive agents, including radiotherapy. Malignant conditions, e.g., lymphoma, leukaemia, Hodgkin’s disease or other tumours of the micro-endothelial system. Clinical (symptomatic) AIDS. Primary or secondary immunodeficiency: HIV-infection, including infants born to HIV-positive mothers. The effect of BCG vaccination may be exaggerated in these patients, and a generalised BCG-infection is possible.

In geographical areas of high risk of contracting tuberculosis and HIV is high, it may be appropriate to vaccinate asymptomatic HIV-positive patients with BCG, according to WHO recommendations.

Vaccination should normally be postponed in persons with moderate or severe acute illness, with or without fever. Mild common illnesses are NOT contraindications to vaccination. Generalised infected skin conditions. Eczema is not a contraindication; however the site of vaccination should be free of lesions.

Special warnings and precautions for use
The vaccine should be administered only by the intradermal route.

The vaccine should preferably be administered by person trained in the intradermal vaccination technique. Too deep injections increase the risk of lymphadenitis and abscess formation.

Tuberculin positive persons should not be vaccinated with BCG vaccine. Administration of the vaccine to such persons may result in an aggravated local reaction.

Allergic reactions to vaccine components are rare, facilities for its management should always be available during vaccination.

Whenever possible, persons should be kept under observation for 15-20 minutes after vaccination, in case an allergic reaction should occur.

Pregnancy and lactation
Although no harmful effects to the foetus have been associated with BCG, vaccine, vaccination is not recommended during pregnancy or lactation. However, in areas with high risk of tuberculosis infection, BCG Vaccine may be given during pregnancy or lactation if the benefit of vaccination outweighs the risk.

Dosage and method of administration
FOR INTRADERMAL USE ONLY

Dosage
Infants under 12 months of age: 0.05 ml (1/20 of 1 ml).

Adults and children aged 12 months and older: 0.1 ml (1/10 of 1 ml).

Handling
The needle stopper of the vial should normally NOT be sealed with any antiseptic or detergent. If the stopper is clogged with any antiseptic or detergent, the vial may be reconstituted without the rubber stopper, it must be allowed to evaporate before the stopper is penetrated with the syringe needle. Using a syringe fitted with a long needle, transfer to the wall the volume of Diluted Sauton 135 stated on the label. Gently swirl the vial with the mixed vaccine before drawing up each subsequent dose. DO NOT SHAKE THE VIAL. When drawn up, the syringe should appear as a homogenous, slightly opaque and colourless suspension.

Method of administration
The mixed vaccine should be administered with a syringe of 1 ml graduated into hundredths of millilitres (1/100) filled with a short broad syringe needle (25G or 26G).

Jet injection or multiple puncture devices should NOT be used to administer the vaccine.

The injection site should be clean and dry. If alcohol or similar is used to swab the site, it must be allowed to evaporate before injection.

The vaccine must be given intradermally, approximately one third down the upper arm corresponding to the area of the distal insertion of the deltoid muscle, as follows:

- The skin is stretched between thumb and forefinger.
- The needle should be almost parallel with the skin surface and slowly inserted with the bevel upward, approximately 2 mm into the superficial layers of the skin. The needle should be visible through the skin during insertion.
- The vaccine should be administered slowly.
- The appearance of a blanched blist is a sign of correct injection technique.
- The injection site is best left uncovered to facilitate healing.

The expected reaction to successful vaccination with BCG Vaccine includes induration and mild erythema at the injection site, followed by a local lesion that may ulcerate some weeks later and heal over some months. The vaccination may also include a less than 1 cm enlargement of regional (poplar) lymph nodes. The ulcer should be encouraged to dry and abscise (by tight clothes, for example) avoided.

A small flat scar will eventually develop after 2-3 months as a result of a successful vaccination.

Over dosage or incorrect administration

Adverse reactions

Infrequently observed effects:
- Fever and headache
- Enlargement of regional lymph node > 1 cm
- Injection site reactions with severe erythema and tenderness
- Ulceration with a discharging ulcer at the site of injection

Rare side effects
- Suppurative lymphadenitis, abscess formation
- Disseminated BCG complications as abscesses or osteomyelitis
- Allergic reactions, including anaphylactic reactions.

During post-marketing safety surveillance symptoms among patients receiving injections have been reported. Also sepsis and convulsions have been reported infrequently.

Interactions

The vaccine can be administered at the same time as other vaccines, but should not be given into the same arm.

If not given at the same time an interval of not less than four weeks should elapse between the administrations of any two live vaccines.

Treatment of inadvertent BCG infection with anti-tuberculosis drugs

If inadvertent systemic or persistent local infection with the BCG vaccine occurs, expert advice should be sought regarding the appropriate treatment regimen.

The table below indicates the antibiotic sensitivity for selected anti-tuberculosis drugs towards the Mycobacterium bovis BCG, Danish strain 1331, in terms of the Minimum Inhibitory Concentration (MIC).

<table>
<thead>
<tr>
<th>Drug</th>
<th>Minimum Inhibitory Concentration (MIC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td>0.4 mg/l</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>2.0 mg/l</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>2.0 mg/l</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>2.5 mg/l</td>
</tr>
</tbody>
</table>

For isoniazid the MIC is 0.4 mg/l. There is no consensus as to whether Mycobacterium bovis BCG, Danish strain 1331 should be classified as susceptible, intermediately susceptible or resistant to isoniazid when the MIC is 0.4 mg/l. However, based on criteria set for Mycobacterium tuberculosis, the strain could be considered to be of intermediate susceptibility.

As a rule, the BCG, Danish strain 1331 is resistant to pyrazinamide.

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours). BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage

BCG Vaccine 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, even for shorter periods.

If inadvertent systemic or local infection occurs, the vaccine should be administered as soon as possible (within 24 hours).

Storage