BCG VACCINE SSI

Powder and solvent for suspension for injection.

Mycobacterium bovis BCG (Bacillus Calmette-Guérin, Danish strain 1311), live attenuated.

Read all of this leaflet carefully before you start using this medicine and keep it to give to a doctor, nurse or pharmacist if you are given a new supply of this medicine.

Important information for you.

- If you have found any of the excipients in the vaccine (listed in section 4) you should not be vaccinated with BCG VACCINE SSI.
- If you have a weak immune system (such as lymphoma, leukaemia or HIV disease) the vaccine should be postponed.
- If you have a weakened resistance toward infections due to a disease of your immune system.
- If you are receiving medical treatment that affects the immune response, e.g. corticosteroids or radiotherapy.
- If you have recently received an immunosuppressive treatment in utero or via breast-feeding (e.g. treatment with TNF-α antagonists).
- If you are suffering from any malignant condition (e.g. lymphoma, leukaemia or Hodgkin's disease).
- If your immune status is in question.
- If you are infected with HIV.
- If you are receiving medical treatment against TB.
- If you have been tested for TB infection and the test was found positive vaccination is not required. Vaccination may cause a severe local reaction in that case.

The vaccine should be administered strictly by the intradermal technique.

The vaccine should preferably be administered by personnel trained in the intradermal vaccination technique. Inadequate administered injections, e.g. subcutaneously or intramuscularly, increase the risk of lymphadenitis and abscess formation.

Subcutaneous injection of positive persons should not be vaccinated as this may result in an aggravated local-regional reaction. Although anaphylactic reactions are rare, facilities for its management should always be available during vaccination. Whenever possible, persons should be kept under observation for at least 2–3 minutes after vaccination if an anaphylactic reaction should occur.

BCG vaccination may be given concurrently with inactivated or live vaccines, including combined measles, mumps and rubella vaccines, without restriction if a period of net less than 4 weeks must pass before giving another live vaccine.

Vaccination must be given at least 3 months before a vaccination in the same arm can take place.

Other medicines and BCG VACCINE SSI
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- Other vaccines can be given at the same site as BCG VACCINE SSI at different injection sites.
- Pregnancy, breastfeeding and fertility.
- If you are pregnant or breastfeeding, or if you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being vaccinated with BCG VACCINE SSI.
- Vaccination is not recommended during pregnancy or breast-feeding, although no harmful effects to the unborn or breast-fed child have been associated with BCG VACCINE SSI.

Driving and using machines.

BCG VACCINE SSI has no influence on the ability to drive and use machines.

3 How you are vaccinated with BCG VACCINE SSI.

The doctor or nurse will give the vaccination by injection into the upper layer of the skin. The dose is 0.1 ml for children under 12 months of age and 0.1 ml for adults and children aged 12 months or more. The injection site is best left uncovered to facilitate healing.

The expected reactions to the vaccination include:
- A slight swelling, redness and tenderness at the injection site, followed by a local lesion.
- Some weeks after this lesion will heal leaving a small, flat scar.
- A slight swelling of the lymph nodes in the arm may be experienced.

These are common reactions to the vaccination.

4 Possible side effects.

Like all medicines, BCG VACCINE SSI can cause side effects, although not everybody gets them.

Severe allergic reactions (such as reddening of the face and neck, swelling of the face, throat or neck, which breathing difficulties and collapse) may occur in rare cases (less than 1 in 1,000).

If you observe any of the above reactions contact your doctor immediately.

Other side effects include:

- Uncommon side effects (may occur in less than 1 in 100 people):
  - Fever.
  - Swelling of lymph nodes in the arm in larger than 1 cm across.
  - An oozing ulcer (greater than 2 cm). Headache.
  - Rare side effects (may occur in less than 1 in 1,000 people):
  - Inflammation of lymph nodes, sometimes with oozing ulcers, possibly abscesses.
  - Infection with the bacteria from the vaccine can occur. The infection can spread throughout the body, including the bones. Fainting, seizures and convulsions among patients receiving injections have been observed.

5 How to store BCG VACCINE SSI.

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2°C – 8°C).
- Store in the original package in order to protect from light.
- Do not freeze.

Handling.

The rubber stopper must not be wiped with any anesthetic or detergent. If alcohol used to rub the rubber stopper, it must be allowed to evaporate before the vial is reconstituted with the syringe needle.

Using a syringe fitted with a long needle, transfer the vial to the volume of Diluted Susten SSI stated on the label. Do not use other diluents, as these may damage the vaccine.

Carefully invert the vial a few times to reuspend the hypophial BCG completely.

Do not shake the vial. Gently roll the vial with the reconstituted vaccine before drawing up each subsequent dose.

When drawn up into the syringe the reconstituted vaccine should appear homogenous, slightly opalescent and colourless.

When reconstituted the vaccine should be used within 4 hours.

Method of administration.

The vaccine should be administered by personnel trained in the intradermal technique.

The injection site should be clean and dry.

Antispetic should be used for the administration.

If alcohol is used to swab the skin, it must be allowed to evaporate before the vaccine is injected.

The vaccine must be given strictly intradermally, approximately one third down from the skin to the area of the distal insertion of the defined muscle, as follows:

What is in this leaflet.

1. What BCG VACCINE SSI is and what is it for.
2. Before you are vaccinated with BCG VACCINE SSI.
3. How you are vaccinated with BCG VACCINE SSI.
4. Possible side effects.
5. How to store BCG VACCINE SSI.
6. Contents of the pack and other information.
Do not use the vaccine after the expiry date which is stated on the carton as “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What BCG VACCINE SSI contains

The active substance is:

Freeze-dried powder containing live attenuated bacteria of the type Mycobacterium bovis BCG (Bacillus Calmette-Guérin), Danish strain 1331.

1 ml vaccine contains between 2 - 8 million bacteria.

The excipients are:

Sodium L-glutamyl monohydrate, magnesium sulphate heptahydrate, L-asparagine monohydrate, ferric ammonium citrate, glycerol 85%, citrice acid, monohydrate and water for injection.

This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially ‘sodium-free’.

What BCG VACCINE SSI looks like and contents of the pack

BCG VACCINE SSI consists of a powder and solvent for injection (2-8 x 10^4 bacteria/0.1 ml dose or 1-4 x 10^4 bacteria/0.05 ml dose).

Deep injections increase the risk of discharging air and lymphadenitis and may lead to excessive scar formation. Gross over dosage increases the risk of undesirable BCG complications.

BCG VACCINE SSI in the amber vial is white and crystalline, the powder might be difficult to see due to the small amount of powder in the vial.

Diluted Sauton SSI in the clear vial is in a colourless solution without lyophilisate and absorbs fungus.

The mixed vaccine should appear as a homogenous, slightly opalescent, colourless suspension.

Pack sizes: 5 vials BCG VACCINE SSI + 5 vials Diluted Sauton SSI packed in the same box.

Marketing Authorisations Holder and Manufacturer

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Deep injections increase the risk of discharging air, lymphadenitis and abscess formation.

Treatment of complications after vaccination with BCG VACCINE SSI

Expert advice is sought regarding the appropriate treatment regimen for the management of systemic infections or persistent local infections following vaccination with BCG VACCINE SSI. Antibiotic sensitivity of the BCG strain:

The table below indicates the minimum inhibitory concentrations (MIC) for selected anti-tuberculosis drugs towards the BCG Danish strain 1331 [as determined by Sauton 460].

The MIC for isoniazid is 0.4 mg/l. There is no consensus as to whether Mycobacterium bovis BCG should be classified as susceptible, intermediate 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.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Minimum Inhibitory Concentration (MIC)</th>
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<tbody>
<tr>
<td>Isoniazid</td>
<td>0.4 mg/l</td>
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<tr>
<td>Pyrazinamide</td>
<td>&gt;10 mg/l</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>2.0 mg/l</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>&gt;25 mg/l</td>
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BCG Danish strain 1331 is resistant to pyrazinamide.