BCG Vaccine SSI, powder and solvent for suspension for injection. *Mycobacterium bovis* BCG (Bacillus Calmette-Guérin), Danish strain 1331, live attenuated, 2–8 × 10^5 CFU per dose.

Read all of this leaflet carefully before you receive this vaccine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What BCG Vaccine SSI is and what it is used for
2. Before you receive BCG Vaccine SSI
3. How you are vaccinated with BCG Vaccine SSI
4. Possible side effects
5. How to store BCG Vaccine SSI
6. Further information

1. WHAT BCG VACCINE SSI IS AND WHAT IT IS USED FOR
BCG Vaccine SSI contains bacteria of the type *Mycobacterium bovis* BCG and is used for protection against tuberculosis (TB).
Pharmacotherapeutic group (ATC code): J 07 AN 01.

2. BEFORE YOU RECEIVE BCG VACCINE SSI

a. You should not be vaccinated with BCG Vaccine SSI
   - If you have known allergies to any of the ingredients in the vaccine.
   - If you have a fever or generalised skin infection. In these cases vaccination should be postponed.
   - If you have a weakened resistance toward infections due to a disease in/of your immune system.
   - If you are receiving medical treatment that affects the immune response e.g. corticosteroids, radiotherapy, or are suffering from any malignant conditions (e.g. lymphoma, leukaemia or Hodgkin’s disease).
   - If you have been exposed to immunosuppressive treatment in utero or via breast-feeding (e.g. treatment with TNF-α antagonists)
   - If your immune status is in question
   - If you are infected with HIV.
   - If you are receiving medical treatment against TB.

b. Take special care with BCG vaccine SSI
   - If you have eczema. The vaccination can be given in an eczema-free area.
If you have been skin tested for TB infection and the test was found positive vaccination is not required. Vaccination may cause a severe local reaction in that case.

c. If you are using other medicines, herbal or dietary supplements
   - Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
   - Other vaccines can be given at the same time as BCG Vaccine SSI at different injection sites.
   - There must be an interval of at least 3 months before a vaccination in the same arm can take place.

d. Consumption of food and drinks when you have been vaccinated with BCG vaccine SSI
   - Intake of food and drinks has no influence on the effect of BCG vaccine, since it is administered parenterally.

e. Pregnancy and breast-feeding
   - Inform your doctor if you are pregnant or are breast-feeding.
   - Vaccination is not recommended during pregnancy or breast-feeding, although no harmful effects to the unborn or breastfed child have been associated with BCG Vaccine SSI.

f. 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 of the arm. The dose is 0.05 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 later this lesion evolves into a small ulcer
   - after some months this ulcer will heal leaving a small, flat scar
   - a slight swelling of the lymph nodes in the armpit 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 redness of the face and neck, swelling of the face, throat or neck, skin rash, 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 armpit larger than 1 cm across.
   - An oozing ulcer at the injection site.
- Headache.
Rare side effects (may occur in less than 1 in 1,000 people)
− Inflammation of lymph nodes, sometimes with oozing ulcers, possibly abscess.
− 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BCG VACCINE SSI
− Keep out of the reach and sight of children.
− Do not use BCG Vaccine SSI after the expiry date which is stated on the carton as “EXP”. The expiry date refers to the last day of that month.
− Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
  Powder:
   − Store in a refrigerator (2°C – 8°C).
   − Store in the original package in order to protect from light.
  Solvent:
   − Do not freeze.

6. FURTHER INFORMATION

a. What BCG Vaccine SSI contains
The active substance is:
Dry 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 other ingredients are:
Sodium glutamate, magnesium sulphate heptahydrate, dipotassium phosphate, citric acid, monohydrate, L-asparagine monohydrate, ferric ammonium citrate, glycerol 85% and water for injections.

b. What BCG Vaccine SSI looks like and contents of the pack
BCG Vaccine SSI consists of a powder and solvent for suspension for injection (2–8 × 10⁵ bacteria/0.1 mL dose or 1–4 × 10⁶ bacteria/0.05 mL dose).
The powder 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.
The solvent in the clear vial is a colourless solution without visible particles.
The mixed vaccine should appear as a homogenous, slightly opalescent, colourless suspension.

Pack sizes: 10 vials of BCG Vaccine SSI (0.75 mg BCG powder) + 10 vials of Diluted Sauton SSI (1 mL solvent). BCG Vaccine SSI and Diluted Sauton SSI are packed in two separate boxes.
c. Marketing Authorisation Holder and Manufacturer
Statens Serum Institut,
5 Artillerivej, DK-2300 Copenhagen S, Denmark
tel.: +45 3268 3268
fax: +45 3268 3973
e-mail: serum@ssi.dk

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Statens Serum Institut,
5 Artillerivej, DK-2300 Copenhagen S, Denmark
tel.: +45 3268 3268
fax: +45 3268 3973
e-mail: serum@ssi.dk

d. This leaflet was last approved in \{MM/YYYY\}; version number \{ \}

e. To report any side effect(s):

- **Saudi Arabia:**
  - National Pharmacovigilance and Drug Safety Centre (NPC)
    - Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340
    - Fax: +966-11-205-7662
    - Toll-free phone: 8002490000
    - E-mail: npc.drug@sfda.gov.sa

- **Other GCC States:**
  - Please contact the relevant competent authority.

f. Council of Arab Health Ministers

**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.
The following information is intended for medical and healthcare professionals only

Special warnings and precautions for use
The vaccine is administered strictly by the intradermal route. The vaccine should be administered by personnel trained in the intradermal vaccination technique. Administering the vaccine too deep increases the risk of a discharging ulcer, abscess formation and regional lymphadenitis. Tuberculin-positive persons (consult national recommendations for the definition of a positive tuberculin reaction) do not require the vaccine. Administration of the vaccine to such persons may result in a severe local reaction. Although anaphylactic reactions are rare, facilities for its management should always be available during vaccination. Whenever possible, persons should be observed for an allergic reaction for up to 20 minutes after immunisation. Intradermal BCG vaccination may be given concurrently with inactivated or live vaccines, including combined measles, mumps and rubella vaccines. If not administered simultaneously, an interval of not less than four weeks should be left between the administrations of any two live vaccines. Further vaccinations in the arm used for BCG vaccination must not be given for 3 months due to the risk of regional lymphadenitis.

Handling
The rubber stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, 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 vial the volume of solvent stated on the label. Carefully invert the vial a few times to resuspend the lyophilised BCG completely. Do not shake the vial. Gently swirl the vial with the resuspended vaccine before drawing up each subsequent dose. When drawn up into the syringe the resuspended vaccine should appear homogeneous, slightly opaque and colourless. From a microbiological point of view the product should be used immediately after reconstitution. In use stability in terms of viability has been demonstrated for 4 hours after reconstitution.

Method of administration
BCG Vaccine SSI must be administered by personnel trained in the intradermal technique. The injection site should be clean and dry. If alcohol is used to swab the skin, it must be allowed to evaporate before the vaccine is injected. The vaccine must be injected strictly intradermally in the arm, over the distal insertion of the deltoid muscle onto the humerus (approx. one third down the upper arm), as follows:

- The skin is stretched between thumb and forefinger.
- The needle should be almost parallel with the skin surface and slowly inserted (bevel upwards), approximately 2 mm into the superficial layers of the dermis.
- The needle should be visible through the epidermis during insertion.
- The injection is given slowly.
- A raised, blanched bleb is a sign of correct injection.
- The injection site is best left uncovered to facilitate healing.
BCG Vaccine SSI should be administered with a syringe of 1 mL graduated into hundredths of mL (1/100) fitted with a short bevel syringe needle (25G/0.50 mm or 26G/0.45 mm). Jet injectors or multiple puncture devices should not be used to administer the vaccine.

**Overdose or incorrect administration**
Overdose increases the risk of undesirable BCG complications. Administering the vaccine too deep increases the risk of a discharging ulcer, abscess formation and regional lymphadenitis.

**Treatment of complications after vaccination with BCG Vaccine SSI**
Localised or disseminated infection with *M. bovis* BCG can occur in rare cases upon BCG vaccination. Expert advice should be sought regarding the appropriate medical treatment of such infections. The sensitivity of the BCG strain towards different anti-tuberculosis agents varies.

Antibiotic sensitivity of the BCG strain:
The MIC values (as determined by the Bactec 460 method) for selected anti-tuberculosis agents against the BCG Danish strain 1331 are as follows:

<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>

BCG Danish Strain 1331 is resistant to pyrazinamide.
**Package leaflet: Information for the user**

**BCG Vaccine SSI, powder and solvent for suspension for injection.**  
*Mycobacterium bovis* BCG (Bacillus Calmette-Guérin), Danish strain 1331, live attenuated, 2–8 × 10^5 CFU per dose.

Read all of this leaflet carefully before you receive this vaccine.

- Keep this leaflet. You may need to read it again.  
- If you have any further questions, ask your doctor or pharmacist.  
- This medicine has been prescribed for you. Do not pass it on to others.  
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What BCG Vaccine SSI is and what it is used for  
2. Before you receive BCG Vaccine SSI  
3. How you are vaccinated with BCG Vaccine SSI  
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5. How to store BCG Vaccine SSI  
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#### 1. WHAT BCG VACCINE SSI IS AND WHAT IT IS USED FOR

BCG Vaccine SSI contains bacteria of the type *Mycobacterium bovis* BCG and is used for protection against tuberculosis (TB).  
Pharmacotherapeutic group (ATC code): J 07 AN 01.

#### 2. BEFORE YOU RECEIVE BCG VACCINE SSI

**a. You should not be vaccinated with BCG Vaccine SSI**

- If you have known allergies to any of the ingredients in the vaccine.  
- If you have a fever or generalised skin infection. In these cases vaccination should be postponed.  
- If you have a weakened resistance toward infections due to a disease in/of your immune system.  
- If you are receiving medical treatment that affects the immune response e.g. corticosteroids, radiotherapy, or are suffering from any malignant conditions (e.g. lymphoma, leukaemia or Hodgkin’s disease).  
- If you have been exposed to immunosuppressive treatment in utero or via breast-feeding (e.g. treatment with TNF-α antagonists).

**b. Take special care with BCG vaccine SSI**

- If you have eczema. The vaccination can be given in an eczema-free area.
If you have been skin tested for TB infection and the test was found positive vaccination is not required. Vaccination may cause a severe local reaction in that case.

c. If you are using other medicines, herbal or dietary supplements
   Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
   Other vaccines can be given at the same time as BCG Vaccine SSI at different injection sites.
   There must be an interval of at least 3 months before a vaccination in the same arm can take place.

d. Consumption of food and drinks when you have been vaccinated with BCG vaccine SSI
   Intake of food and drinks has no influence on the effect of BCG vaccine, since it is administered parenterally.

e. Pregnancy and breast-feeding
   Inform your doctor if you are pregnant or are breast-feeding.
   Vaccination is not recommended during pregnancy or breast-feeding, although no harmful effects to the unborn or breastfed child have been associated with BCG Vaccine SSI.

f. 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 of the arm. The dose is 0.05 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 later this lesion evolves into a small ulcer
   after some months this ulcer will heal leaving a small, flat scar
   a slight swelling of the lymph nodes in the armpit 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 redness of the face and neck, swelling of the face, throat or neck, skin rash, 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 armpit larger than 1 cm across.
   An oozing ulcer at the injection site.
- Headache.
Rare side effects (may occur in less than 1 in 1,000 people)
- Inflammation of lymph nodes, sometimes with oozing ulcers, possibly abscess.
- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BCG VACCINE SSI
- Keep out of the reach and sight of children.
- Do not use BCG Vaccine SSI after the expiry date which is stated on the carton as “EXP.”
  The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
  Powder:
  – Store in a refrigerator (2°C – 8°C).
  – Store in the original package in order to protect from light.
  Solvent:
  – Do not freeze.

6. FURTHER INFORMATION

a. 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 other ingredients are:
Sodium glutamate, magnesium sulphate heptahydrate, dipotassium phosphate, citric acid, monohydrate, L-asparagine monohydrate, ferric ammonium citrate, glycerol 85% and water for injections.

b. What BCG Vaccine SSI looks like and contents of the pack
BCG Vaccine SSI consists of a powder and solvent for suspension for injection (2–8 × 10^5 bacteria/0.1 mL dose or 1–4 × 10^5 bacteria/0.05 mL dose).

The powder 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.
The solvent in the clear vial is a colourless solution without visible particles.
The mixed vaccine should appear as a homogenous, slightly opalescent, colourless suspension.

Pack sizes: 10 vials of BCG Vaccine SSI (0.75 mg BCG powder) + 10 vials of Diluted Sauton SSI (1 mL solvent). BCG Vaccine SSI and Diluted Sauton SSI are packed in two separate boxes.
c. Marketing Authorisation Holder and Manufacturer
Statens Serum Institut,
5 Artillerivej, DK-2300 Copenhagen S, Denmark
tel.: +45 3268 3268
fax: +45 3268 3973
e-mail: serum@ssi.dk

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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5 Artillerivej, DK-2300 Copenhagen S, Denmark
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d. This leaflet was last approved in {MM/YYYY}; version number { }

e. To report any side effect(s):

- Saudi Arabia:
  - National Pharmacovigilance and Drug Safety Centre (NPC)
    - Call NPC at +966-11-2038222, Ext.: 2317-2356-2353-2354-2334-2340
    - Fax: +966-11-205-7662
    - Toll-free phone: 8002490000
    - E-mail: npc.drug@sfda.gov.sa

- Other GCC States:
  - Please contact the relevant competent authority.

f. Council of Arab Health Ministers

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.
The following information is intended for medical and healthcare professionals only

Special warnings and precautions for use
The vaccine is administered strictly by the intradermal route. Administering the vaccine too deep increases the risk of a discharging ulcer, abscess formation and regional lymphadenitis.

Tuberculin-positive persons (consult national recommendations for the definition of a positive tuberculin reaction) do not require the vaccine. Administration of the vaccine to such persons may result in a severe local reaction. Although anaphylactic reactions are rare, facilities for its management should always be available during vaccination. Whenever possible, persons should be observed for an allergic reaction for up to 20 minutes after immunisation.

Intradermal BCG vaccination may be given concurrently with inactivated or live vaccines, including combined measles, mumps and rubella vaccines. If not administered simultaneously, an interval of not less than four weeks should be left between the administrations of any two live vaccines.

Further vaccinations in the arm used for BCG vaccination must not be given for 3 months due to the risk of regional lymphadenitis.

Handling
The rubber stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, 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 vial the volume of solvent stated on the label. Carefully invert the vial a few times to resuspend the lyophilised BCG completely. Do not shake the vial. Gently swirl the vial with the resuspended vaccine before drawing up each subsequent dose.

When drawn up into the syringe the resuspended vaccine should appear homogeneous, slightly opaque and colourless.

From a microbiological point of view the product should be used immediately after reconstitution. In use stability in terms of viability has been demonstrated for 4 hours after reconstitution.

Method of administration
BCG Vaccine SSI must be administered by personnel trained in the intradermal technique. The injection site should be clean and dry.

If alcohol is used to swab the skin, it must be allowed to evaporate before the vaccine is injected. The vaccine must be injected strictly intradermally in the arm, over the distal insertion of the deltoid muscle onto the humerus (approx. one third down the upper arm), as follows:

- The skin is stretched between thumb and forefinger.
- The needle should be almost parallel with the skin surface and slowly inserted (bevel upwards), approximately 2 mm into the superficial layers of the dermis.
- The needle should be visible through the epidermis during insertion.
- The injection is given slowly.
- A raised, blanched bleb is a sign of correct injection.
- The injection site is best left uncovered to facilitate healing.
BCG Vaccine SSI should be administered with a syringe of 1 mL graduated into hundredths of mL (1/100) fitted with a short bevel syringe needle (25G/0.50 mm or 26G/0.45 mm). Jet injectors or multiple puncture devices should not be used to administer the vaccine.

**Overdose or incorrect administration**

Overdose increases the risk of undesirable BCG complications. Administering the vaccine too deep increases the risk of a discharging ulcer, abscess formation and regional lymphadenitis.

**Treatment of complications after vaccination with BCG Vaccine SSI**

Localised or disseminated infection with *M. bovis* BCG can occur in rare cases upon BCG vaccination. Expert advice should be sought regarding the appropriate medical treatment of such infections. The sensitivity of the BCG strain towards different anti-tuberculosis agents varies.

Antibiotic sensitivity of the BCG strain:

The MIC values (as determined by the Bactec 460 method) for selected anti-tuberculosis agents against the BCG Danish strain 1331 are as follows:

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<th>Drug</th>
<th>Minimum Inhibitory Concentration (MIC)</th>
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BCG Danish Strain 1331 is resistant to pyrazinamide.