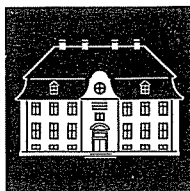


BCG Vaccine SSI

Powder and solvent for suspension for injection.



STATENS
SERUM
INSTITUT

Read the entire leaflet carefully before you receive this vaccine.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or nurse.

5, Artillerivej
2300 Copenhagen S
Denmark

This leaflet tells you:

1. What BCG Vaccine SSI is and what it is used for
2. Before you receive BCG Vaccine SSI
3. How BCG Vaccine SSI is administered
4. Possible side effects
5. How to store BCG Vaccine SSI

The full name of your vaccine is:

BCG Vaccine SSI Bacillus Calmette-Guerin (BCG) vaccine Vaccine against tuberculosis Powder and solvent for suspension for injection

BCG Vaccine SSI is a freeze-dried, white crystalline powder containing the bacteria *Mycobacterium bovis* BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated as the active substance.

The powder might be difficult to see due to the small amount in the vial. The vaccine powder is mixed with the solvent, Diluted Sauton SSI, before use. Diluted Sauton SSI is a colourless solution without any visible particles.

1 ml of the vaccine contains between 2 and 8 million live units of *Mycobacterium bovis* BCG.

The other ingredients are sodium glutamate, magnesium sulphate heptahydrate, dipotassium phosphate, L-asparagine monohydrate, ferric ammonium citrate, glycerol, citric acid monohydrate and water for injections.

Manufacturer and marketing authorisation holder
Statens Serum Institut, 5, Artillerivej, DK-2300 Copenhagen S.

1. What BCG Vaccine SSI is and what it is used for

BCG Vaccine SSI is a vaccine used for protection against tuberculosis.

The vaccine contains live bacteria called *Mycobacterium bovis*. These bacteria belong to the same family of bacteria that causes tuberculosis (TB).

Mycobacterium bovis bacteria can cause infections in cattle. They very rarely cause infections in humans. The *Mycobacterium bovis* bacteria in the vaccine have been weakened so that they do not cause disease when they are injected into the skin of healthy people.

After vaccination, the BCG vaccine reacts with the immune system. The immune system is then able to protect you against infection with the bacteria that cause TB in humans.

TB is spread between humans mainly by inhaling bacteria that are exhaled or spat out by individuals who have an active TB lung infection. Most infections start in the lungs but can spread throughout the body if the infection is not treated properly.

BCG Vaccine SSI cannot completely prevent infections that cause TB. If BCG Vaccine SSI is administered to someone already infected with TB but not showing any symptoms, the vaccine cannot prevent the infection from spreading.

2. Before you receive BCG Vaccine SSI

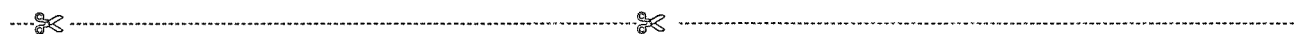
If the answer to any of the questions below is "YES" for the person who is to be vaccinated, BCG Vaccine SSI should not be administered. If you have any doubts, ask your doctor or nurse.

- Are you allergic to any of the ingredients of the vaccine?
- Do you have a fever or generalised skin infection? If so, vaccination should be postponed until the fever or infection has cleared.
- Do you have weakened resistance to infections or is your immune system not functioning properly? For example, are you undergoing treatment with steroids, receiving medication or treatment that weakens the immune system (including radiotherapy) or suffering from any malignant conditions (e.g. lymphoma, leukaemia or Hodgkin's disease)?
- Are you infected with HIV that causes AIDS? Individuals infected with HIV but who are well may be vaccinated with BCG if there is a high risk of catching TB.
- Are you taking medicines against TB?

Take special care with BCG Vaccine SSI:

Inform your doctor or nurse if the answer to any of the following questions is "YES" for the individual who is to be vaccinated. Your doctor or nurse will decide if you can receive BCG Vaccine SSI.

- Do you have eczema? BCG Vaccine SSI can still be given into an area of normal skin if the eczema in other areas is not infected.
- Have you had a positive skin test for TB infection? BCG Vaccine SSI is not helpful in such cases and there can be problems at the injection site.



The following information is intended for medical or healthcare professionals only:

BCG Vaccine SSI is used for active immunisation against tuberculosis.

BCG Vaccine SSI is to be used on the basis of national official recommendations.

Composition

One dose for children aged 12 months and over, adults and elderly contains between $2-8 \times 10^5$ cfu.

One dose for infants under 12 months of age contains between $1-4 \times 10^5$ cfu.

Reconstitution

Only Diluted Sauton SSI may be used for reconstitution of BCG Vaccine SSI.

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 Diluted Sauton SSI given on the label. Carefully invert the vial a few times to resuspend the lyophilised BCG completely. DO NOT SHAKE. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose.

The reconstituted vaccine should be used immediately.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

Method of administration

When drawn up into the syringe the vaccine suspension should appear homogenous, slightly opaque and colourless. BCG Vaccine SSI should be administered with a syringe fitted with a short bevel needle (gauge 25 or 26 G).

Jet injectors or multiple puncture devices should not be used to administer the vaccine.

The injection site should be clean and dry and not contaminated with antiseptics. If alcohol is used to swab the skin, it must be allowed to evaporate before the vaccine is injected.

The vaccine should be injected strictly intradermally in the arm, over the distal insertion of the deltoid muscle onto the humerus (approximately 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 with the bevel upward, approximately 2 mm into the superficial layers of the dermis.
- The needle should be visible through the epidermis during insertion.
- The injection should be given slowly.
- A raised, blanched bleb is a sign of correct injection.
- The injection site is best left uncovered to facilitate healing.

Dosage

Children aged 12 months and over, adults and elderly:

A dose of 0.1 ml of the reconstituted vaccine is injected strictly by intradermal injection. National recommendations should be consulted regarding the need for tuberculin testing prior to administration of BCG Vaccine SSI.

Pregnancy and breast-feeding:

Inform your doctor if you are pregnant, believe you may be pregnant or are breast-feeding. In areas with high risk of TB infection, BCG may be administered during pregnancy or lactation if the benefit of vaccination outweighs the risk.

Driving and using machines:

BCG Vaccine SSI has no or negligible influence on the ability to drive and use machines.

Taking other medicines:

Please inform your doctor if you are taking or have recently taken any other medicines, whether these have been prescribed or bought without a prescription.

Having other vaccines:

BCG Vaccine SSI may be given simultaneously, at a separate site, with all other vaccines and immunoglobulins.

Other vaccines can be administered at the same time as BCG Vaccine SSI, but at different injection sites. If other live vaccines are not administered simultaneously, they are normally administered with at least an interval of one month. No other vaccines should be injected into the arm where BCG Vaccine SSI was administered for three months after the injection.

If you have any questions about whether you should have other vaccines, ask your doctor or nurse.

3. How BCG Vaccine SSI is administered

For children at least 12 months of age, adults and elderly a dose of BCG Vaccine SSI is 0.1 ml (a very small amount of liquid). For children less than 12 months of age the dose is 0.05 ml.

The vaccine is usually injected into the upper arm. A small scar usually remains after a successful vaccination. Your doctor or nurse will ensure that the vaccine is injected correctly into the skin and not the muscle or into a blood vessel.

The injection site is best left uncovered to facilitate healing. If you experience any persisting discomfort in or around the injection site, if you feel generally unwell or if you notice any swelling of the glands in your armpit or anywhere else, you should contact your doctor or nurse for advice. See also Possible Side Effects below.

Since BCG Vaccine SSI will be administered by a doctor or nurse, it is very unlikely that you may receive too much or too little of the vaccine.

If you think you may not have had the correct dose, ask your doctor or nurse. Having more vaccine than is necessary can increase the risk of discomfort at the injection site. Having less vaccine than is necessary may leave you unprotected against TB.

4. Possible side effects

Like all medicines, BCG Vaccine SSI can have side effects. The expected reaction to a successful vaccination with BCG Vaccine SSI includes a slight swelling at the injection site followed by a small ulcer. It will heal over some months leaving a small, flat scar. You may also experience some swelling of glands in the armpit, less than one centimetre across. These are normal reactions to the vaccine.

Inform your doctor or nurse, if you have persisting swelling at the injection site, a slow healing ulcer or swelling in your armpit larger than one centimetre across. These are not normal reactions to the vaccine.

Uncommon side effects (happens to more than one in a thousand people but less than one in one hundred people)

- Headache.
- Fever.
- Swelling of glands in the armpit to more than 1 cm across.
- A running ulcer at the injection site. If this happens, the ulcer should be allowed to dry and tight clothes should be avoided. If the ulcer seems very slow to heal, contact your doctor or nurse for advice.

Rare side effects (happens to less than one in a thousand people but more than one in ten thousand people)

- Inflammation of glands, sometimes with abscesses and release of fluid from the swellings.
- Infection with the bacteria in the vaccine (*Mycobacterium bovis* BCG) can occur. This can spread throughout the body, including to the bones. This does not usually happen in people who are otherwise healthy. This infection has to be treated.
- Severe allergic reactions can occur (such as redness of the face and neck, swelling of the face, throat or neck, skin rash, breathing difficulties and collapse). These often start very soon after the injection and may happen while you are still in the clinic. If the symptoms start after leaving the clinic, contact a doctor or visit a casualty ward urgently.

If you experience any side effects not mentioned in this leaflet, please inform your doctor.

5. How to store BCG Vaccine SSI

BCG Vaccine SSI must be stored in a refrigerator at 2°C - 8°C, protected from light. The expiry date specified on the label must not be exceeded. Do not freeze the solvent, Diluted Sauton SSI. Once the solvent has been mixed with vaccine, it should be administered immediately.

BCG Vaccine must be kept out of the reach and sight of children.

This leaflet was last approved on 21-07-2004

Infants under 12 months of age:

A dose of 0.05 ml of the reconstituted vaccine is injected strictly by intra-dermal injection.

Interactions

BCG may be given simultaneously, at a separate site, with all other vaccines and immunoglobulins. Other vaccines to be given at the same time as BCG Vaccine SSI should not be given into the same arm. If not given at the same time, an interval of not less than four weeks should normally be allowed to lapse between the administrations of any two live vaccines. No further vaccination should be given for at least three months in the arm used for BCG vaccination, because of the risk of regional lymphadenitis.

Contraindications

BCG Vaccine SSI should not be administered to persons known to be hypersensitive to any component of the vaccine.

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

BCG Vaccine SSI should not be given to persons receiving systemic corticosteroids or immunosuppressive treatment including radiotherapy, to those suffering from malignant conditions (e.g., lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system), those with primary or secondary immunodeficiencies, those with 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 areas where the risk of contracting tuberculosis and HIV is high, it may be appropriate to vaccinate asymptomatic HIV-positives with BCG

according to WHO recommendations. BCG Vaccine SSI should not be given to patients who are receiving prophylactic doses of anti-tuberculous drugs.

Special warnings and precautions for use

Although anaphylaxis is very rare, facilities for its management should always be available during vaccination. Whenever possible, patients should be observed for an allergic reaction for up to 15-20 minutes after receiving immunisation.

Tuberculin positive persons do not require the vaccine. Administration of the vaccine to such persons may result in a severe local reaction. An excessive response to the BCG Vaccine SSI may result in a discharging ulcer. This may be attributed to inadvertent subcutaneous injection or to excessive dosage. Injections made too deeply may also increase the risk of lymphadenitis and abscess formation.

Precautions in case of overdose

Overdose in infants increases the risk of suppurative lymphadenitis and may lead to excessive scar formation. If a disseminated infection with BCG occurs, systemic treatment with a suitable antituberculous drug should be considered. Expert medical advice should be obtained on management and treatment. In-vitro testing has shown that BCG SSI (Danish Strain 1331) is susceptible to isoniazid and rifampicin.

Storage

BCG Vaccine SSI must always be stored at 2°C-8°C. Store in original package in order to protect from light. The expiry date specified on the label must not be exceeded. Do not freeze Diluted Sauton SSI. The reconstituted vaccine should be used immediately.