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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).

2. What you need to know before you are vaccinated with BCG Vaccine SSI
You should not be vaccinated with BCG Vaccine SSI
• If you have known allergies to any of the components in the vaccine (listed in section 6)
• If you are suffering from an acute severe febrile illness 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 or radiotherapy

The following information is intended for medical and healthcare professionals only
Special warnings and precautions for use
The vaccine should be administered strictly by the intradermal route.
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.
Tuberculin skin test positive persons should not be vaccinated as this may result in an aggravated loco-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 15-20 minutes after vaccination, in case an allergic reaction should occur.
BCG vaccination may be given concurrently with inactivated or live vaccines, including combined measles, mumps and rubella vaccines. If not given concurrently a period of not less than 4 weeks must pass before giving another live vaccine.
There must be an interval of at least 3 months before a vaccination in the same arm can take place.

Handling
The rubber stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab 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 vial the lyophilised BCG completely. Do not use other diluents, as these may damage the vaccine. Carefully invert the vial a few times to the resuspend the lyophilised BCG completely. Do not shake the vial. Gently swirl 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 opaque 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. If antiseptics (such as alcohol) are applied to swab the skin, it must be allowed to evaporate before injection.
The vaccine must be given strictly intradermally, approximately one third down the upper arm corresponding to the area of the distal insertion of the deltoid muscle, as follows:
- If you have been exposed to immunosuppressive treatment in utero or via breast-feeding (e.g. treatment with TNF-α antagonists)
- If you are suffering from any malignant conditions (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

The doctor or nurse will be extra cautious about vaccinating you with BCG Vaccine SSI
• If you have a disease in/of your immune system
• 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 site.

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 time as BCG Vaccine SSI at different injection sites

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think 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 breastfed 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 0.05 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
• 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 consult 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 oozy 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 oozy 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.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BCG Vaccine SSI

- Keep this medicine out of sight and reach of children
- Store in a refrigerator (2ºC - 8ºC)
- Do not freeze
- 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-Guerin), Danish strain 1331.

1 ml vaccine contains between 2-8 million bacteria.

The excipients are:

- Sodium glutamate, magnesium sulphate, diphosphates, L-asparagine monohydrate, ferric ammonium citrate, glycerol 85%, citric acid, monohydrate and water for injections.

**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 x 10^9 bacteria/0.1 ml dose or 1-4 x 10^9 bacteria/0.05 ml dose). Pack sizes of 1, 5, or 10 vials and pack size of 1 vial with one syringe and two injection needles (one long for adding solvent and one short for intradermal injection).

**Administration of the vaccine**

**This leaflet was last revised in 06/2015**