

New Zealand Consumer Medicine Information

BCG VACCINE SSI

Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, 2-8 x 10⁵ cfu powder and solvent for suspension for injection.

What is in this leaflet

This leaflet answers some common questions about BCG Vaccine SSI. It does not contain all the available information. It does not take the place of talking to your doctor or nurse.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BCG Vaccine SSI against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or nurse.

Keep this leaflet with the medicine. You may need to read it again.

What BCG Vaccine SSI is used for

BCG Vaccine SSI is a vaccine which provides active immunisation against tuberculosis. Tuberculosis (TB) is a disease caused by infection with the bacteria (germ) *Mycobacterium Tuberculosis*. TB can damage a person's lungs or other parts of the body and cause serious illness.

BCG Vaccine SSI is a dried powder containing bacteria which are very similar to the organisms which cause tuberculosis. The bacteria in the medicine has been altered so that they produce only a mild localised infection but at the same time cause your body to build up resistance to tuberculosis.

Your doctor may have prescribed BCG Vaccine SSI for another reason. Ask your doctor or nurse if you have any questions about why BCG VACCINE SSI has been prescribed for you.

Before you are given BCG Vaccine SSI

When you must not use it

Do not take BCG Vaccine SSI if:

- you are sensitive (allergic) to any of the ingredients listed at the end of this leaflet
- you are receiving anti-tuberculosis drug
- you had an allergic reaction to a previous dose of BCG Vaccine
- you have fever
- you have a general skin infection
- you have a HIV infection or are in a high risk group but have not been tested for HIV
- you have an impaired immune system
- you are receiving immunosuppressive treatment (a treatment that lowers the body's resistance to disease for e.g. corticosteroids that affect the entire body or radiotherapy)

- it is after the expiry date (EXP) printed on the pack. If you take this medicine after the expiry date has passed, it might not work as well
- the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor or nurse if:

- you have ever had tuberculosis. You have a positive tuberculin (Mantoux) test. This is a test which shows whether you have had tuberculosis or BCG vaccine previously
- you are pregnant, are breast-feeding or planning to breast-feed. BCG Vaccine SSI is not recommended during pregnancy and while breastfeeding
- you have had other vaccines in the past four weeks.

If you have not told your doctor about any of the above, tell them before you use BCG Vaccine SSI.

Taking other medicines

Tell your doctor if:

- you have received another vaccine within the last 4 weeks
- **you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

How BCG Vaccine SSI is given

A doctor or nurse gives BCG Vaccine SSI as an injection (approximately one third down the upper arm).

How much is given

Dose for infants below 12 months is 0.05 mL. Dose for adults and children over 12 months of age is 0.1 mL of the reconstituted vaccine.

When it is given

“Pre-exposure”:

BCG Vaccine SSI is given in advance to people at risk of being infected with tuberculosis.

Overdose

Overdose is not likely because your doctor or nurse will give you the injection. If you have any concerns, ask your doctor.

If you think you or anyone else may have been given too much of this medicine

- Consult your doctor immediately or,
- Telephone the National Poisons Centre (0800 764 766) for advice, or
- Go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

Side Effects

Tell your doctor or nurse as soon as possible if you or your child does not feel well after having BCG Vaccine SSI.

Ask your doctor or nurse to answer any questions you may have.

All medicines, including vaccines can have side effects. BCG Vaccine SSI may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or nurse if you notice any of the following and they worry you:

- Pain, swelling, redness and heat or a hard lump may form at the site of the injection. The area may become painful and an ulcer may form. This gets better without any treatment. A small, flat scar may form when the ulcer heals
- Pus formation at the site of injection
- Swollen glands in the groin, armpit, neck, under the jaw and chin, behind the ears or on the back of the head may form as a result of the body building protection
- Headache
- Fever.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- Bone pain, general discomfort, uneasiness, or ill-feeling, chills, excessive sweating, low back pain, swelling of the ankles, feet and legs
- If the glands remain swollen, tender or do not get smaller after several weeks or continue to get larger and are greater than 1 cm, contact your doctor.

ALLERGIC reaction:

As with all vaccines given by injection, there is a very small risk of a severe allergic reaction.

Some people get other side effects while using BCG Vaccine SSI. Tell your doctor if you notice any unwanted side effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by BCG Vaccine SSI.

After Using BCG Vaccine SSI

Storage

BCG VACCINE SSI is usually stored in the doctor's clinic, or at the pharmacy. However, if you need to store BCG Vaccine SSI:

- **Keep it where children cannot reach it.**
- **Keep it in the original pack to protect from light, until it is time for it to be injected.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze. Reconstituted vaccine may be kept cold for up to four hours, protected from light.**

Product Description

What it looks like

Each pack of BCG Vaccine SSI contains powder and solvent for injection.

The powder vial consists of a white, crystalline powder. The solvent vial has a colourless solution without any visible particles.

Active Ingredient

Mycobacterium bovis (BCG), Danish strain 1331, $2-8 \times 10^5$ cfu (*colony forming units*).

Other ingredients

Powder:

Sodium glutamate

Solvent:

L-Asparagine monohydrate

Citric acid monohydrate

Dipotassium phosphate

Ferric ammonium citrate

Glycerol 85%

Magnesium sulphate pentahydrate

Water for injections

Supplier

BCG VACCINE SSI is distributed in New Zealand by:

Seqirus (NZ) Ltd

PO Box 62 590

Greenlane

Auckland 1546

New Zealand

This leaflet was prepared in December 2017.