

BCG VACCINE

Consumer Medicine Information

This leaflet contains information about BCG (Bacillus Calmette-Guérin) Vaccine. Please read it carefully and keep for future reference. The information in this leaflet is only a summary and is not intended to replace advice from your doctor. Please consult your doctor if you have any comments or questions.

What Is BCG Vaccine?

BCG Vaccine is a vaccine which will give partial protection against tuberculosis. Whilst it is not 100% effective, it makes it much more likely that you will get a mild localised infection rather than an overwhelming life-threatening illness if you should become infected with tuberculosis.

Tuberculosis is relatively rare in Australia now, but in the days when it was common, all children received BCG Vaccine; this is one of the reasons why the number of cases of tuberculosis has decreased. In populations where tuberculosis is still common, such as in some Canadian Indians, BCG Vaccine has been shown to protect 60% of those children who have been vaccinated.

What does BCG Vaccine contain?

BCG Vaccine is a dried powder containing bacteria which are very similar to the organisms which cause tuberculosis, but have 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. The dry powder also contains monosodium glutamate.

Before giving the injection, your doctor will mix the powder with sterile water which contains:

- Sodium chloride
- Sodium phosphate, monobasic
- Sodium phosphate, dibasic anhydrous
- Polysorbate 80

What happens when you have BCG Vaccine?

After mixing the powdered bacteria with the liquid, your doctor will inject a very small amount into the skin of your arm or thigh.

In 1 to 3 weeks a small red lump appears at the place where you had the injection. This then turns into a small blister which is soon replaced by a crusty scab. When this heals and drops off, a small scar remains. The whole event is usually painless and does not make you feel ill. It is a good idea to cover the blister and then the scab with a dry adhesive type dressing to stop it getting infected or soiling your clothes.

Swollen glands may occur near the site of Injection, especially in newborn babies.

BCG vaccination is successful in at least 90% of people. If you have ever had tuberculosis or a successful BCG vaccination you become what is known as

tuberculin positive. This means that if you have a tuberculin skin test it produces a small red swollen reaction. If you are tuberculin positive you do not need BCG Vaccine.

When should BCG Vaccine be used?

As very few people in Australia are now suffering from tuberculosis, universal vaccination of children is not necessary. People who have tuberculosis in their lungs and are spreading tuberculosis germs every time they cough can quickly spread the disease to unprotected individuals. In these circumstances BCG Vaccine can help to protect people of any age.

BCG Vaccine should be used in the following situations:

- Newborn Aboriginal and Torres Strait Islander babies in areas where tuberculosis is common.
- Newborn babies, if either parent has leprosy.
- Children under 5 years old who will travel or live in countries where tuberculosis is common.

BCG Vaccine is considered helpful in the following situations:

- Newborn babies who are living in a house with people from countries where tuberculosis is common.
- Children and adolescents under 16 who are in contact with a patient with tuberculosis where the infection is resistant to treatment or the child or adolescent cannot take the appropriate antibiotic.

BCG Vaccine may be helpful in the following situations:

- If you are a health worker and are in contact with patients with tuberculosis.
- Travellers over 5 years old who will spend a long time in a country where tuberculosis is common.

When should BCG Vaccine not be used?

It is not necessary to use BCG Vaccine routinely in Australia at this time.

BCG should not be given if:

You have tuberculosis.

You have ever had tuberculosis.

You have a fever.

You suffer from skin conditions such as eczema or dermatitis

You have HIV disease or are in a high risk group but have not been tested for HIV.

You have received another live vaccine within 4 weeks.

You are receiving immunosuppressive treatment.

You have a positive tuberculin (Mantoux) test. This is a test which shows whether you have had tuberculosis or BCG Vaccine previously. (See "What happens when you have BCG Vaccine?").

What should you tell your Doctor?

You should tell your doctor:

1. If you have ever had any form of tuberculosis.
2. If you have ever been vaccinated with BCG.
3. If any relative or friend now has or has ever had tuberculosis.
4. If you are pregnant (Pregnancy Category B2).
5. About any illness that you now have.
6. About any previous severe illnesses.
7. Whether you are taking any medicines.

Are there any side effects?

As with any medicine some side effects may occur.

The amount of inflammation at the site of the injection may vary from person to person. Sometimes a quite severe reaction can occur with pain and swelling. This usually gets better without any treatment. Severe reactions are often accompanied by swelling of the glands in the armpit (or in the groin if the injection was in the leg). Larger scars may be formed after large reactions.

In children with eczema or adults with severe skin conditions the BCG may spread to involve other areas (See "When should BCG Vaccine not be used?").

Widespread BCG infection can occur very rarely following BCG vaccination, usually in immunosuppressed people. In some cases deaths have occurred.

You should report to your doctor any problems that you encounter after receiving the vaccine.

What is the dose of BCG Vaccine?

After mixing the powder with the liquid, the dose of BCG Vaccine is 0.1 mL in adults and children over 1 year and 0.05 mL in children under 12 months of age.

It is not usually necessary to have a second injection of BCG Vaccine except in children aged 12 to 15 years who were vaccinated as infants and have a negative Tuberculin test (See "What happens when you have BCG Vaccine?").

Where can I get more information?

You can get more information from your doctor or pharmacist.

How should BCG Vaccine be stored?

BCG Vaccine should be protected from light and stored between 2° and 8°C (in the refrigerator). Do not freeze the vaccine.

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Aust R Number

Aust R 53569

Date of preparation

27 August 2007