BCG VACCINE

BCG VACCINE, Bacillus Calmette and Guérin

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 Aboriginal 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. The stopper of the vial contains latex.

Before giving the injection, your doctor will mix the powder with sterile water which contains sodium chloride, sodium phosphate - dibasic, sodium phosphate - monobasic and 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.

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.

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 (Mantoux) 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 are spreading tuberculosis germs every time they cough and they 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:

- Aboriginal and Torres Strait Islander newborn 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 years of age who are in contact with a patient with tuberculosis where the infection is resistant to treatment, and where 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 Vaccine should not be given if:

- You have an allergy to BCG Vaccine or any of the ingredients, including latex (See “What does BCG Vaccine contain”).
- You had an anaphylactic or other allergic reaction to a previous dose of BCG Vaccine.
- You have tuberculosis.
- 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. (See “What happens when you have BCG Vaccine?”).
- 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 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?”).
- You have received another live vaccines within 4 weeks.

What should you tell your doctor?

You should tell your doctor:

- If you have ever had any form of tuberculosis.
- If you have ever been vaccinated with BCG Vaccine.
- If any relative or friend now has or has ever had tuberculosis.
- If you are pregnant.
- About any illness that you now have.
- About any previous severe illnesses.
- 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. Larger scars may be formed after large reactions.

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

Sudden severe allergic reactions, for which symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylactoid reactions) have been reported rarely following administration of BCG Vaccine.

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 at 2° to 8°C (in the refrigerator). Do not freeze the vaccine.
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