



INFORMATION FOR PARENTS/CARERS

IMPORTANT – PLEASE READ: THIS INFORMATION IS ABOUT THE BCG
VACCINE YOUR CHILD IS ABOUT TO RECEIVE

Unlicensed BCG Vaccine (Freeze Dried) supplied by InterVax Ltd, Canada

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- If your child has any side effects that appear serious, or concern you, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4 for more details.

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

BCG is a vaccine, used for protection against tuberculosis (TB), as part of the UK national vaccination programme. It contains a weakened strain of a bacteria called *Mycobacterium bovis* and, as with most vaccines, it works by mimicking a natural infection. Because it is weakened it doesn't actually cause TB, but it helps your child develop immunity against TB.

This brand of BCG vaccine is supplied by InterVax Ltd, and manufactured by BB-NCIPD Ltd. In the UK it is being supplied as an unlicensed product, which means it does not have a valid marketing authorisation (licence) in the UK. This vaccine is being provided in accordance with medicines legislation that allows an unlicensed medicine to be supplied when a licensed alternative is not available and the Medicines and Healthcare Products Regulatory Agency (MHRA) has not objected to its importation.

Although InterVax Ltd and BB-NCIPD Ltd have not applied to license the product in the UK, it is a WHO prequalified vaccine meaning it can be used around the world for immunisation against TB. It is also licensed in other EU countries. This product can be prescribed by an eligible healthcare provider to protect your child from TB.

2. How the vaccine is given

The doctor or nurse will give the vaccination by injection into the top layer of the skin on the upper left arm.

The dose is 0.05 ml for infants under 12 months of age and 0.1 ml for adults and children aged 12 months or more.

3. Important precautions for BCG vaccination

If you think any of these apply to you or your child it is important to let the doctor or nurse know before the vaccine is given.

Your child should not be vaccinated with BCG Vaccine:

- If they have been previously treated for TB
- If they have known allergies to any of the components in the vaccine (listed in section 5)

- If they have a weakened resistance toward infections due to a disease or illness in their immune system
- If they are receiving medical treatment that affects the immune response
- If you have received a medicine during pregnancy, or during breastfeeding, that has weakened your immune system and could have been passed on to your child
- If they are infected with HIV
- If they have already had BCG vaccination
- If your child has been tested for TB infection using the Mantoux (skin) test and found positive, as vaccination may cause a severe local reaction.

Additional precautions

- If your child is suffering from an acute severe febrile illness, vaccination may be post-poned until your child is better
- If your child has eczema. The vaccination can be given in an eczema-free area.

Other medicines and BCG Vaccine

Tell your doctor if you are taking, have recently taken or might take any other medicines. This is important if you are breastfeeding and the vaccine is for your child.

To ensure timely protection InterVax BCG can be given at the same time or at any time before or after other vaccines such as DTaP/IPV+Hib and hepatitis B vaccines.

Other vaccines to be given at the same time as InterVax BCG vaccine should not be given into the same arm. It is advisable not to give further vaccination in the arm used for BCG vaccination for 3 months.

BCG can be administered at the same time as other live vaccines including rotavirus, live attenuated influenza vaccine (LAIV), oral typhoid vaccine, yellow fever, varicella, zoster and MMR.

For further information, see this link: www.gov.uk/government/publications/updated-recommendations-for-administering-more-than-1-live-vaccine.

Pregnancy

Vaccination is not recommended during pregnancy, although no harmful effects to the unborn or breastfed child have been associated with BCG Vaccine. If you are pregnant, think you may be pregnant or are planning to have a baby and the vaccine is intended for you, ask your doctor for advice before being vaccinated with BCG vaccine.

4. Common reactions to BCG vaccination

Like all medicines, BCG Vaccine can cause side effects, although not everybody gets them.

A local reaction where the vaccine was given is expected following BCG vaccination, which may include:

- A slight swelling, redness and tenderness at the injection site followed by a local papule (small raised blister)
- Some weeks later this small raised blister may change into a small ulcer
- This ulcer should heal completely without treatment in a several weeks

The injection site is best left uncovered to help healing.

Possible side effects

A slight swelling of the lymph nodes in the armpit may occasionally be experienced.

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. If you observe any of these reactions contact your doctor immediately.

Severe injection site reactions such as large, local discharging ulcers or abscesses. If you observe any of these reactions contact your nurse/doctor.

Other adverse reactions to the vaccine include headache, fever and swelling of a regional lymph node (e.g. in the armpit) to greater than 1cm and which may ulcerate.

Severe complications due to spread of the vaccine in the body (such as in the bones) are rare.

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist, midwife or nurse. This includes any possible side effects not listed in this leaflet. You should report side effects to the Yellow Card Scheme at: yellowcard.mhra.gov.uk

5. Contents of the pack and other information

What InterVax BCG Vaccine contains

The active substance is:

Freeze-dried powder containing live attenuated bacteria of the type *Mycobacterium bovis* BCG (Bacillus Calmette-Guerin).

A 0.05 ml dose of BCG vaccine contains between 75,000 – 300,000 viable bacterial units.

The other components in a 0.05 ml paediatric dose are:

In the freeze dried powder:

- Sodium L-glutamate monohydrate (stabilizer) – 0.15 mg

In the diluent:

- Sodium chloride – 0.45 mg
- Water for injection – 0.05 ml

What BCG Vaccine looks like and contents of the pack

BCG is freeze-dried preparation in amber glass ampoules containing a maximum of 10 adult (or 20 infant) doses, sealed under vacuum. The final packing is a box with two blister-type carriers, each of which contains 10 ampoules of BCG vaccine. The diluent is in ampoules, containing 1 ml Sodium Chloride 9 mg/ml. The final packing of diluent is also a box with two blister-type carriers, each of which contains 10 ampoules.

The mixed vaccine should appear as a homogenous suspension free of particulate matter.

Supplier

InterVax Ltd., 625 Cochrane Drive, Suite #802
Markham, Ontario L3R 9R9 CANADA
www.intervax.com
Tel: (905) 940-8385
Fax: (905) 940-8387

Manufacturer

BB-NCIPD Ltd., 26 Yanko Sakazov Blvd.,
1504 Sofia, Bulgaria
Tel: +359 2 944 61 91
Fax: +359 2 943 34 55
E-mail: bulbio@bulbio.com



Public Health
England

PHE enquiries

Enquiries@phe.gov.uk

© Crown copyright 2018

3208385 5p 130K Apr 2018 (APS)

This medicinal product is World Health Organisation (WHO) approved.

This leaflet was last revised in 02/2017