

BCG 10 Anti-Tuberculosis Vaccine

Information for patients and their families

BCG vaccine is in short supply worldwide. The product registered for use in Australia is not currently available.

An alternative product BCG 10 vaccine is available for use under special arrangements.

Patients or parents/guardians should understand the information provided before proceeding with use of this product.

Last updated: June 2016

What is BCG 10 Anti-Tuberculosis Vaccine?

- BCG vaccine is in short supply globally and Australia's BCG supply expired in December 2015.
- An alternative product, which is currently not registered for use in Australia, is being offered under special prescribing arrangements to people who require BCG vaccine.
- This product has been manufactured in Poland since 1955, and is registered in Poland.
- Australia's medicines regulatory body, the Therapeutic Goods Administration (TGA), has advised that this product is also supplied to other European countries, although not registered there.
- A Good Manufacturing Practice (GMP) certificate has been issued by the authorities in Poland.
- The TGA has approved supply of this product on the basis of this GMP certificate, indicating that the vaccine is manufactured under acceptable quality and safety conditions. However, as is the case for other products supplied under these special prescribing arrangements, the TGA advises that they cannot accept liability for safety, quality or efficacy of this vaccine.
- Patients or their parent/guardian are required to give informed consent before BCG 10 is administered (see [BCG Vaccination: Information for Parents](#)).

Is this product safe for me/my child?

- As this is an unregistered BCG product, NSW Health has consulted with the National Centre for Immunisation Research and Surveillance (NCIRS) and the National TB Advisory Committee (NTAC).
- NCIRS advised that all available evidence suggests that this product is suitable for use, and that BCG 10 is likely to provide a similar level of protection against TB as other BCG products.
- Persons receiving BCG vaccine should be aware that there is a risk of side effects with any BCG vaccine product used, whether it is a registered product or not.
- Available evidence indicates that the rate of side effects with BCG 10 vaccine should be no greater than that associated with other BCG products.
- Any adverse effects from the BCG vaccine should be reported to your vaccine provider.
- Alternatively you can report adverse reactions to the TGA. More information on reporting adverse events is available from the TGA website. <http://www.tga.gov.au/safety/problem.htm#medicine>

Please discuss any further questions you have with your vaccine provider before proceeding.