

MeNZB™ Vaccine Licensed

What is the significance of this announcement?

Licensure of the MeNZB™ vaccine means authorised vaccinators can administer the vaccine to children and young people aged between six months and 19 years in a large-scale immunisation programme. The immunisation programme could not progress without the vaccine being licensed and approved for use.

What is the licensure process?

Before any medicine or vaccine can be used in New Zealand, the manufacturer must receive consent from the Minister of Health, or the person to whom she has delegated this authority. Medsafe, New Zealand's Medicines and Medical Devices Safety Authority is the authority responsible for regulating all medicines in the country. Medsafe has assessed safety, quality and efficacy data about the vaccine and sought international peer review of its findings before presenting its recommendation to the Minister. Details of the licence for MeNZB™ vaccine are published in The Gazette, published by the New Zealand Gazette Office. When the licence has been gazetted, the medicine can be legally distributed and administered.

Why is the Counties Manukau area of Auckland the first to receive vaccine?

Since the epidemic began, this area has consistently had the highest rates of meningococcal disease. Providing vaccine to this area early in the immunisation programme means that more cases of meningococcal disease can be prevented and the effect of the epidemic reduced.

When will the immunisation programme begin in other areas?

As soon as everything is in place. It is expected that the programme will launch in greater Auckland later in 2004. The Ministry of Health has notified all District Health Boards in New Zealand about the meningococcal immunisation programme and each is responsible for planning in their own area. It is expected that Northland DHB will begin vaccinating later in 2004 and that all North Island DHBs will begin vaccinating in the first half of 2005. South Island DHBs are expected to start vaccinating in mid 2005.

What happens next?

The Ministry of Health and the project team based at Counties-Manukau District Health Board will begin promoting the Meningococcal B Immunisation Programme in the Counties Manukau area of Auckland and some high-risk suburbs of eastern Auckland District Health Board. Advertising, a website and 0800 phone line will be launched to support the immunisation programme. Information will be distributed to the public health units and primary care providers that will be involved in the first stage of the immunisation programme. Information will be sent to primary care providers throughout the rest of the country shortly, and more detailed information to follow as the vaccine roll out progresses. Information for the public will be widely available through District Health Boards, primary health providers and schools.

What does the vaccine do?

It helps to prevent meningococcal B disease by stimulating the body to increase its immunity to the bacteria that causes the disease. However people will need to watch out for the signs and symptoms of meningococcal disease because the vaccine will not give protection from other strains of the disease and some people may not develop a high level of protection.

What should people do to get the vaccine?

School students whose parents sign a consent form will be immunised by a public health nurse at school. The nurses will contact each school student through the school when the vaccine is available to them in their area.

Children under five years, children not attending school and young people who have left school will be immunised by a doctor or practice nurse at their family doctor, Māori health service, Pacific health service, outreach service, student health service or occupational health clinic. They will be contacted when the immunisation programme will begin in their area. If they are not enrolled with a Primary Health Organisation or general practitioner, they should contact one of these services to find out when the MeNZB™ immunisation programme will begin.

When is the vaccine due to expire

Most of the vaccine currently in New Zealand is due to expire at the end of April 2005. It is unlikely that there will be any unused stock of MeNZB™ on this date. Medsafe has evaluated data about the vaccine's stability as part of the licensure application and has assigned an 18-month shelf life.

What is the 0800 free phone number?

0800 20 30 90. (live from midday Friday 8th July)

What is the website address?

<http://www.moh.govt.nz/meningococcal>

What is meningococcal disease?

A bacterial infection that can cause serious illnesses including meningitis (an infection of the membranes that cover the brain) and septicaemia (a serious infection in the blood). For every 100 people that get meningococcal disease, on average:

- 4 will die
- 20 will suffer a permanent and serious physical disability
- others will have ongoing behavioural or learning difficulties.

A person who has meningococcal disease can deteriorate very quickly (sometimes less than 24 hours), so it is important to get urgent medical help if meningococcal disease is suspected.

How many people have been affected?

- There have been more than 5400 cases of meningococcal disease since the epidemic began in 1991. To date, there have been 220 deaths caused by meningococcal disease.

Who is affected by meningococcal disease?

Meningococcal disease can affect anyone but 80 out of every 100 cases occur in people aged 0-19 years. About half of all cases occur in children aged under five years. Babies are most at risk.

Rates among Māori and Pacific peoples are extraordinarily high. On average, Māori contract meningococcal disease at double the rate of Europeans. Pacific peoples are affected at four times the rate of Europeans. People of other ethnicity make up a very low proportion of cases, but all are at high risk .

The bacteria that cause meningococcal disease are carried by about one in every five people. It is not known why some people can carry the bacteria but don't become sick, while other people suffer the disease.