

THE MENINGOCOCCAL B IMMUNISATION PROGRAMME: A RESPONSE TO AN EPIDEMIC

*ko koe ki tēnā kō au ki tēnei kiwei ō te kete
Kia tūhauora ki tua ō rangi*

Working together for a healthy future

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MENINGOCOCCAL B – BE WISE, IMMUNISE

MEETING THE CHALLENGE: SAVING YOUNG LIVES!

The Meningococcal B Immunisation Programme (the 'programme') aims to control the specific strain of group B meningococcal disease that has reached epidemic proportions in New Zealand.

To implement an immunisation programme that achieves the target of 90% vaccination coverage in all New Zealanders aged under 20 years and reduces inequalities for Māori and Pacific peoples and those living in more deprived areas, we will need to harness the energy, drive, collaboration and leadership found within the New Zealand health sector.

It is recognised that the additional workload associated with a multiple dose immunisation programme of this size, will create pressure for the health sector. However given the goal is to save young lives, it is imperative that the Ministry, District Health Boards (DHBs) and immunisation providers and health professionals rise to the challenge.

With your help and a climate of collegiality, openness and lots of hard work, the programme will be successful in reducing the incidence of group B meningococcal disease and halting the epidemic.

For further information regarding the programme please phone your DHB Meningococcal B Immunisation Programme Project Manager, Local Immunisation Co-ordinator or District Immunisation Facilitator, or 0800 20 30 90.

Yours sincerely



Dr Jane O'Hallahan
Director
Meningococcal B Immunisation Programme

KEY MESSAGES

1. Meningococcal disease can affect everyone, but children and young people under 20 years of age are most at risk.
 - Pacific children have a 1:66 chance of getting meningococcal disease before their fifth birthday
 - Tamariki Māori have a 1:117 chance of getting meningococcal disease before their fifth birthday
 - European and other children have a 1:438 chance of getting meningococcal disease before their fifth birthday.
2. MeNZB™ vaccination is free.
3. Three doses of MeNZB™ vaccine are required at intervals of six weeks.
4. All three doses of MeNZB™ vaccine are required for protection.
5. The MeNZB™ vaccine is like a 'designer label' as it is exclusive and precious. Because MeNZB™ vaccine supplies are limited, please treat it with care. Do NOT freeze it, protect it from light and order carefully (do not stockpile).

WE NEED YOUR HELP TO MAKE THIS PROGRAMME A SUCCESS

Please:

- support the programme
- make access to the MeNZB™ vaccine as easy as possible
- actively promote MeNZB™ immunisation.

1.0 MENINGOCOCCAL DISEASE

Meningococcal disease is caused by *Neisseria Meningitidis*¹. At least 13 groups of *N. meningitidis* have been differentiated to date. Groups A, B and C cause most disease, and are responsible for nearly all outbreaks of disease. The human upper respiratory tract is the only known reservoir for *N. meningitidis* and it is transmitted by aerosol or secretions to others.



Five to 15 percent of individuals are asymptomatic nasopharyngeal carriers of strains of *N. meningitidis* (this figure can be as high as 50% in specific communities), most of which are not disease causing, ie, disease is the unusual outcome. Usually carriage is brief, however some people may carry the organism for months or years.

The meningococcus causes a wide range of diseases, but most commonly meningitis and or septicaemia (meningococcaemia). Meningococcal invasive disease usually has a sudden onset with fever, malaise, prostration and a variety of other possible symptoms including nausea, vomiting and headache. The illness may be non-specific in young infants.

The signs and symptoms of meningococcal meningitis do not differ widely from those caused by *Haemophilus Influenzae* type b or *Streptococcus Pneumoniae* meningitis. In an aggressive or raging infection with bleeding into the skin and organs (fulminant infectious purpura), shock, coma and death can occur in a few hours despite appropriate treatment.

Approximately two-thirds of cases have a rash, which may be petechial, purpuric or (less commonly) maculopapular. The presence of a petechial or purpuric (haemorrhagic) rash must be taken very seriously. Invasive meningococcal disease can also give rise to arthritis, myocarditis, pericarditis, endophthalmitis and pneumonia. Other presentations include primary pneumonia, occult bacteraemia, conjunctivitis and chronic meningococcaemia.

THE IMPACT OF MENINGOCOCCAL DISEASE:

For every 100 children who get meningococcal disease:

- 100 will spend from 2 – 50 days in hospital
- 4 will die
- 5 to 20 will develop severe brain damage or deafness. They may lose limbs or be left with damaged skin that needs extensive skin grafts
- 25 will be left with long-term learning or behavioural difficulties
- 60 will survive unharmed.

¹ Photo courtesy of Professor K. Cartwright, 1995

New Zealand has low case fatality rate of 4 – 5% per annum, as compared to approximately 10% in other countries. Our low case fatality rate is largely due to the early recognition and management of the disease manifestations by health professionals throughout New Zealand.

More detailed information on meningococcal disease can be found on the Ministry of Health website: www.moh.govt.nz or the Meningococcal B Immunisation Programme website www.immunise.moh.govt.nz.

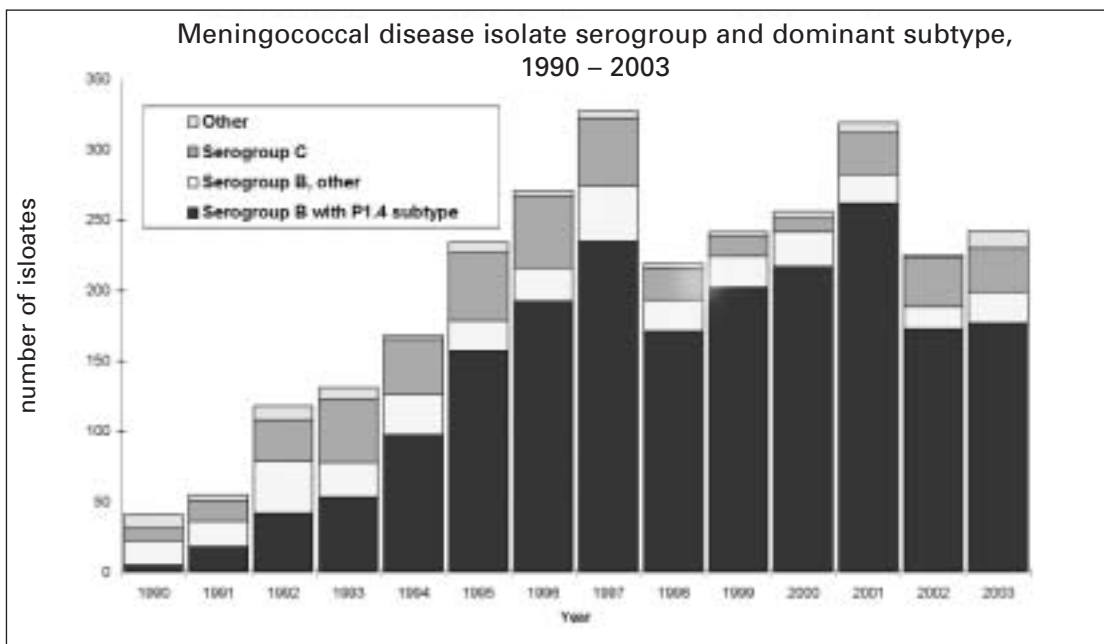
2.0 THE NEW ZEALAND SITUATION

Invasive meningococcal disease is at epidemic proportions in our population and is New Zealand's most serious communicable disease problem, as measured by the size and impact of the epidemic.

In 2004 New Zealand entered its 14th year of a widespread epidemic of group B meningococcal disease. Group B strains have dominated over the past 25 years, with the exception of the group A outbreak that occurred in Auckland from 1986-1987 and isolated group C outbreaks in Wellington and Taranaki in 1994, and in Otago in 2002-2003.

In the second half of 1991 a group B strain, identified as B:4:P1.7b,4 caused a sudden increase in the number of cases of the disease. Since 1995 the proportion of group B isolates of this strain, has averaged 80-90% annually. The dominance of this epidemic type over all other meningococci is graphically demonstrated below.

FIGURE 1



REGIONAL DISEASE BURDEN

The greatest number of cases occurs in northern New Zealand. In the past five years:

- 19.8% of all cases have occurred in south Auckland
- 45% of cases have occurred from Waikato north
- 70% of cases have occurred from Hawkes Bay north
- Only 18% of cases occurred in the South Island.

At June 2004, more than 5400 cases had been notified since the start of the epidemic, with 220 deaths recorded. Every month's delay without a vaccine programme means approximately 50 cases and 2 deaths.

Meningococcal disease disproportionately affects children and young people, with more than 80% of cases occurring in those aged 0 -19 years. Our youngest are at greatest risk.

New Zealand children have a one in 330 risk of contracting this disease by the age of five years. Māori and Pacific children, and those living in deprived areas, bear a disproportionately high share of the disease burden.

In 2003 the provisional age-standardised disease rate for Māori infants (aged under one year) was 4.7 times the rate seen in European infants, while the rate for Pacific infants was 11.5 times that of European infants.

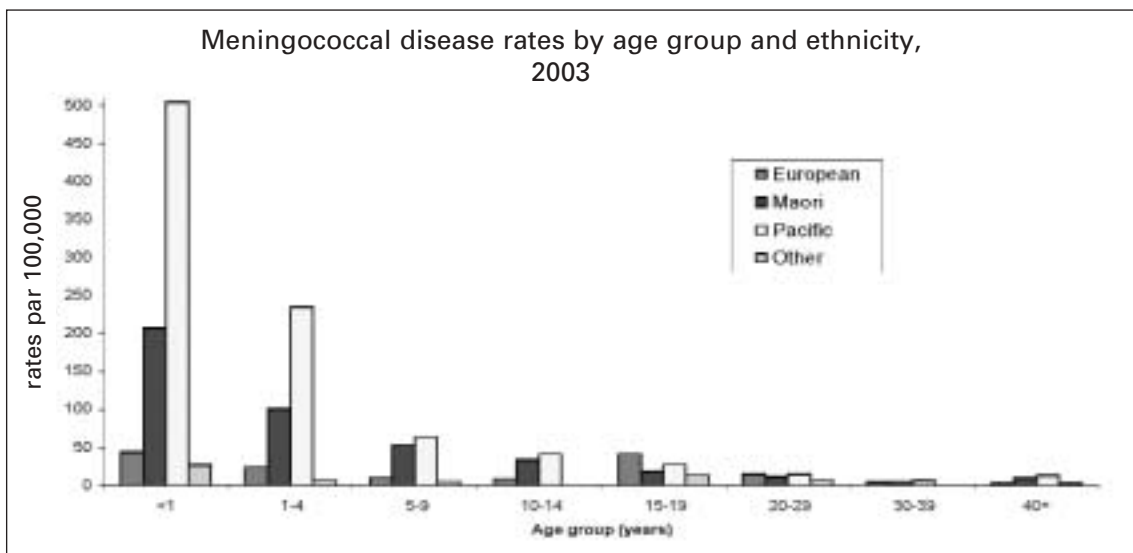


FIGURE 2

A FEW FACTS ABOUT RISK FACTORS FOR MENINGOCOCCAL DISEASE

[Based on data from the Institute of Environmental Science and Research Limited (ESR)]

Data from 1998-2002

- Māori and Pacific children make up 65-69% of all meningococcal cases in the group aged 0-4 years. These young children make up a third of all cases in those aged 0-19 years.

Data from 2002

- Children aged 0-4 years living in New Zealand's most deprived areas (NZ Dep Index 9 or 10) accounted for 107 (47%) of all meningococcal cases in this age group.
- Children and young people aged 0-19 years who live in NZ Dep Index 9 and 10 areas accounted for 158 (38%) of all cases in this age group.
- Children aged 0-4 years who are Māori, Pacific or living in areas classified NZ Dep Index 9 or 10 areas accounted for 166 (72%) of all meningococcal cases in this age group. These young children make up approximately 40% of all cases in those aged 0-19 years.
- Children and young people who are Māori or Pacific or who live in NZ Dep Index 9 and 10 areas accounted for 259 (62%) of all cases in the group aged 0-19 years.

3.0 THE MENINGOCOCCAL B IMMUNISATION PROGRAMME

The Meningococcal B Immunisation Programme implementation is aligned to:

- vaccine production
- the requirement for intensified safety monitoring in the early stages of the programme
- the implementation of the National Immunisation Register (NIR).

The Meningococcal B Immunisation Programme is commencing in the Counties Manukau District Health Board² and a geographically defined 'eastern corridor'³ of Auckland District Health Board.

The programme will then progress DHB by DHB from greater Auckland and Northland through to Wellington in the North Island, then from Southland through to Nelson-Marlborough in the South Island. The nationwide programme implementation generally targets districts with the highest disease rates first. (The nationwide implementation plan can be found in Appendix 1).

The programme is being undertaken with intensive post-licensure safety monitoring, post-licensure evaluation of effectiveness, careful monitoring of coverage using the NIR and School-Based Vaccination System (SBVS) and formal programme evaluation.

WHO IS ELIGIBLE FOR THE MeNZB™ VACCINE?

1. Infants, children and young people aged from six weeks to 19 years of age⁴ are eligible for the programme. A young person is still eligible to receive MeNZB™ vaccine⁵ if they are 20 years of age or over, as long as their first dose was given when they were under 20 years of age and the immunisation date is within the programme timeframe.
2. The immunisation information of children and young people receiving MeNZB™ vaccine must be submitted to the National Immunisation Register (NIR), either automatically or manually in the required timeframe.
3. Children and young people who do not wish to have their information entered into the NIR will not be eligible for MeNZB™ immunisation.

The reasons for this are related to monitoring for safety and effectiveness purposes. National surveillance is mandatory for safety requirements and is part of a population safety strategy. Recording all events on the NIR enables tracking the vaccine uptake nationally for any side effects that may occur either immediately or over longer periods of time. It means that hospital discharge data can be matched nationally and any 'new signals' or trends detected very quickly.

If an individual declines MeNZB™ immunisation, this information may be recorded on the NIR or the individual may choose to 'opt off' the collection of the decline information [i.e. only their National Health Index (NHI) number, date of birth, District Health Board resident in, date of opt off and any immunisation events recorded before they opted-off is retained on the NIR].

2 South Auckland has been selected for the first stage of the nationwide programme because of the high rates and numbers of meningococcal disease cases.

3 Eastern Corridor refers to Glen Innes East, Glen Innes West, Glen Innes North, Hamlin, Mt. Wellington North, Mt. Wellington South, Otahuhu East, Otahuhu West, Panmure Basin, Point England, Tamaki.

4 On July 8, 2004, MeNZB™ vaccine was licensed for use in children six months and older. On 3 February 2005, the minimum age MeNZB™ is licensed for was reduced to six weeks. Initially, only infants aged over 6 weeks in the Auckland, Waitemata and Counties Manukau DHBs are eligible for MeNZB™ vaccine. It is expected that infants aged over 6 weeks elsewhere in New Zealand will become eligible about May 2005. Please refer to the addendum on pages 39 and 40 for details. If in doubt about eligibility, please call 0800 20 30 90 toll free.

5 MeNZB™ vaccine means the New Zealand group B meningococcal vaccine manufactured and trademarked worldwide by Chiron Vaccines (a division of Chiron Corporation).

4. Any infant, child or young person aged up to 20 years of age who has a documented history of suspected or confirmed meningococcal disease should still receive MeNZB™ immunisation. This is because there is no guarantee that they had the epidemic strain or that illness confers immunity.

The Eligibility Policy (Appendix 2) also covers other issues including place of residence, movement between primary care and public health nursing services, children who move districts during the programme and foreign or non-resident fee-paying students.

WHAT ARE THE SERVICE DELIVERY ARRANGEMENTS?

The programme service delivery arrangements:

1. Children under five years of age, children not attending school and young people who have left school will be immunised by a doctor or nurse from:
 - their family health service / general practice
 - Māori health service
 - Pacific health service
 - an outreach immunisation service
 - a student health service
 - an occupational health clinic.

Children who commence their MeNZB™ immunisation course with a primary care provider and have their fifth birthday before the course is completed should complete it in primary care.

2. Children and young people attending primary, intermediate and secondary school, will be immunised by public health nursing services at school unless they meet one of the criteria listed below:
 - the child or young person has a bleeding disorder
 - the child or young person has a documented history of anaphylaxis with cardio respiratory symptoms
 - the child or young person has a documented history of worsening episodes of allergic symptoms due to any cause
 - the school-based campaign has been completed and the child or young person has been 'missed'
 - the child or young person has had a MeNZB™ dose in the school-based campaign but has since left school.

3. Responsibility for the child or young person completing (and being offered the opportunity to complete) the MeNZB™ course remains with the initial provider, unless there is a formal transfer (written) to another provider. For example, this might be a primary care provider to an Outreach Immunisation Service (OIS), public health nursing services to a primary care provider or an OIS.
4. DHB approved Outreach Immunisation Services will be involved in the promotion of the MeNZB™ vaccine and provide immunisation services to children who are not being reached by primary care immunisation providers.

WHAT POINTS SHOULD PROVIDERS⁷ GIVE CONSIDERATION TO WHEN PLANNING FOR THE PROGRAMME?

When planning how to accommodate the programme, providers will decide the best option for their practice. However when undertaking their planning, providers may like to consider the following points:

1. immunising children under five years of age first and immunising young people over 16 years of age once the immunisation of children under five years has been or is nearly completed
2. the time taken to deliver the programme. The programme requires three injections with six-week intervals between injections
3. how many children and young people could be vaccinated per week
4. how the practice will manage MeNZB™ immunisations each week, eg, dedicated days (full days), clinics (2 – 4hrs duration), or as part of routine work
5. how appointments will be scheduled, eg, individual appointments or open days / clinics
6. how the practice will inform parents and young people of the need for and availability of, MeNZB™ vaccine, eg, recall letters, phone calls
7. the space involved in managing the additional numbers of patients and family members / whānau waiting and staying for the 20 minutes after MeNZB™ immunisation.

⁶ Public Health Nurses may be called rural health nurses in some areas.

⁷ “Providers” refers to primary care providers, outreach immunisation providers, public health nursing services, student health services and other health providers as determined by the Ministry.

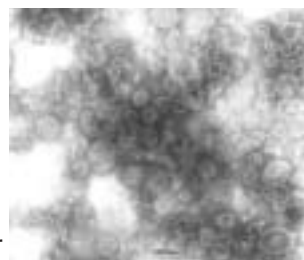
4.0 THE VACCINE – MeNZB™

The New Zealand meningococcal B vaccine, MeNZB™, is strain specific to New Zealand and will not protect for meningococcal A or C or other strains of B. Therefore it is essential that people continue to be aware of the signs and symptoms of meningococcal disease and seek medical help quickly.

The MeNZB™ vaccine is manufactured by Chiron Corporation and the information in this section has been sourced from the MeNZB™ vaccine leaflet that can be found in the vaccine box.

WHAT TYPE OF VACCINE IS MeNZB™?

MeNZB™ vaccine is an outer membrane vesicle⁸ (OMV) vaccine. The active components in the vaccine are the vesicles (proteins) from the outer (cell) wall of the New Zealand strain of meningococci.



There are no live meningococcal bacteria in MeNZB™ vaccine and it is not possible to catch the disease, or to become a carrier of the disease, from the vaccine.

MeNZB™ vaccine contains:

- aluminium hydroxide as the adjuvant
- histidine buffer to stabilise (maintain) the pH of the vaccine
- normal saline.

MeNZB™ vaccine does not contain:

- the preservative thiomersal
- egg product
- Neomycin
- human blood or bovine products.

Like all vaccines, MeNZB™ vaccine has undergone testing to ensure that it conforms to the specifications detailed by the manufacturer.

WHAT SAFETY MONITORING REQUIREMENTS HAVE BEEN PUT IN PLACE FOR MeNZB™ VACCINE?

Vaccines are generally given to a large number of healthy people to prevent disease. Therefore, a very high standard of safety is generally expected of vaccines.

A similar vaccine made in Norway and using the same technology has been given in over 300,000 doses in Norway, most of these during controlled studies, with an excellent safety and effectiveness profile. Other meningococcal B vaccines have been given in over 40 million doses, primarily in Latin America, with no serious unexpected reactions recorded.

The MeNZB™ vaccine has been safely used in clinical trials in Auckland with a range of age groups, including babies and adults, and has been licensed for distribution.

⁸ Electron micrograph of outer membrane vesicles in the Norwegian Meningococcal B vaccine. Picture courtesy of Ingeborg Aaberge of the Norwegian Institute of Public Health.

A comprehensive system of safety surveillance has been put in place around the introduction of the MeNZB™ vaccine. As is the case with any vaccine, adverse events will occur following MeNZB™ immunisations. The safety monitoring system has been designed to ensure extensive safety monitoring of the vaccine post-licensure, firstly to detect serious adverse events following immunisation, secondly to enable assessment of a causal versus a temporal (coincidental) relationship with immunisation, and thirdly to increase public confidence in the programme.

During the first stage of the roll out, surveillance teams at Auckland/Starship, Middlemore/Kidz First and Whangarei hospitals will monitor hospital admissions and emergency department consultations to identify pre-selected conditions.

Routine health professional reporting to the Centre for Adverse Reaction Monitoring (CARM) will be enhanced, including the intensive monitoring of visits in the six weeks following immunisation for children aged 6 weeks to 18 months at pre-selected sentinel general practices throughout New Zealand.

Routinely collected hospital discharge data from all regions will also be reviewed to monitor for specified events following introduction of MeNZB™. An Independent Safety Monitoring Board has been established by the Health Research Council to review all safety data.

HOW EFFECTIVE IS THE MeNZB™ VACCINE?

MeNZB™ vaccine may not protect every person who receives the three doses but it is expected that most people will be protected. While the exact period is unknown, protection is expected to last for a number of years.

The method used for measuring the immune response to meningococcal vaccines is the serum bactericidal assay (SBA), which mimics the complement-mediated response that occurs naturally following infection. The SBA has been used to measure immune response in natural immunity to polysaccharide antigens, and (most recently) with the use of group C vaccine in the United Kingdom. A good immune response to a vaccine (a 'sero-response') is usually defined as a fourfold rise in SBA antibody titre following immunisation.

Data from the MeNZB™ vaccine studies shows that of the participants who had three doses of MeNZB™ given at six week intervals, 75% toddlers and 91% adults developed a fourfold rise (compared with pre-vaccination values) in serum bactericidal antibody titres 4-6 weeks after the third dose. The remaining participants in studies are likely to have increased protection against the epidemic strain (development of serum bactericidal antibody), just not a four-fold rise.

While a 'protective' level of serum bactericidal antibody (SBA_b) has not been established for outer membrane vesicle (OMV) group B vaccines such as MeNZB™, it could well be lower than a fourfold rise.

A number of observational studies are planned post-licensure to assess the effectiveness of the vaccine.

WILL THE MeNZB™ VACCINE CAUSE REACTIONS?

Injection site reactions are a known and expected immune response to all vaccines. Following the administration of MeNZB™ vaccine, most people can expect to have a mild to moderate injection site reaction usually lasting 2 – 3 days, but in a few cases it may last longer. All injection site reactions will completely resolve.

MeNZB™ injection site reactions include:

- pain or tenderness
- temporary redness
- swelling, and/or
- induration (the hardening of normally soft tissue, especially the skin, because of inflammation).

A MeNZB™ injection site reaction would not constitute an adverse event requiring notification to CARM, unless considered serious or severe.

Other commonly reported reactions to MeNZB™ vaccine include:

- irritability
- sleepiness
- headache
- malaise
- anorexia (change in eating habits)
- myalgia and arthralgia (school children and adults)
- diarrhoea and vomiting (toddlers)
- fever of at least 38.0°C.

In the trials, some children had a day off school after the first vaccination, with fewer having a day off after the second or third dose.

A reaction to one dose does not mean there will be the same reaction to other doses, but it does increase the chance of a similar reaction occurring. Severe reactions of any type are uncommon and there is no evidence from the clinical trials that long-lasting reactions occur. See Appendix 3 for summary information on the frequency of reported reactions across the clinical trials.

Health professionals are advised to manage MeNZB™ reactions and adverse events in the same way they would manage or treat (and report) other vaccine adverse events.

ARE THERE SITUATIONS WHERE MeNZB™ VACCINE SHOULD NOT BE GIVEN OR GIVEN WITH PRECAUTIONS?

Contraindications to the MeNZB™ vaccine are:

- anaphylaxis (type 1 hypersensitivity) reaction to a previous dose of the MeNZB™ vaccine, or to any of its components (refer page 13),
- pregnancy (no clinical data),
- acute illness with significant fever (fever >38°C), and/or systemic upset.

Precautions to the administration of MeNZB™ vaccine are:

- a documented history of anaphylaxis with cardio respiratory symptoms,
- thrombocytopenia or bleeding disorders. The risk of bleeding following an intramuscular injection must be evaluated against the benefit of MeNZB™ immunisation – if in doubt consult the child or young person's specialist,
- children and young people who are prone to seizures should have paracetamol before and for 48 hours after vaccination to reduce the chance of a fever after vaccination bringing on a seizure.

Note:

Those with an immune deficiency disorder are at increased risk of meningococcal infection. As MeNZB™ vaccine is not a live vaccine it should be offered to these people but if in doubt consult the child or young person's specialist.

WHAT COMPRISES A COURSE OF MeNZB™ VACCINE?

The MeNZB™ course comprises three 0.5ml doses with an interval of six weeks between each dose. The vaccine must not be injected intravenously, subcutaneously or intradermally. The vaccine must not be mixed with other vaccines in the same syringe.

The following recommendations are the minimum and maximum interval (between doses) for the Meningococcal B Immunisation Programme.

1. Six weeks should be the planned interval between doses.
2. In rare instances when it is logistically necessary:
 - The interval between dose 1 and 2 could be shortened to four weeks (preferred option) or lengthened to eight weeks; and
 - The interval between dose 2 and 3 could be lengthened to three months. The interval between dose 2 and 3 should not be shortened to less than six weeks.
3. Where an individual has not attended for a subsequent dose at the appropriate time, it is not necessary to repeat prior doses. Simply continue the MeNZB™ vaccine schedule as if no interruption had occurred⁹.

⁹ The standard vaccinology rule is that there is no need to repeat prior doses – simply continue the vaccine schedule as if no interruption had occurred. This rule also applies to MeNZB™ vaccination (Meningococcal Management Team, April 2004).

WHAT DOES THE MeNZB™ VACCINE BOX AND VIAL LOOK LIKE?

MeNZB™ vaccine comes as a single dose in a 3ml glass vial, which is closed by grey rubber stoppers and aluminium overseals, covered with orange flip-off caps. Each vial contains the standard dose of 0.5ml, and there are 10 vials per vaccine box.



MeNZB™ vaccine is an off white opalescent (pearly) suspension. If foreign particulate matter and or variation of the normal physical aspect (off-white, opalescent suspension) is observed, the vaccine should not be used.

A MeNZB™ vaccine box measures 88mmW by 46mm by 36mmD, ie, almost identical in size to a box of MMR vaccine. The box is distinctive from other vaccine packaging, with its light grey, vibrant pink and red colouring.



DOES MENZB™ VACCINE REQUIRE ANY PREPARATION PRIOR TO USE?

MeNZB™ vaccine does not require reconstitution, however as it contains an adjuvant, the vial must be shaken to obtain a uniform suspension prior to the vaccine being drawn up.

As a principle it is recommended that a vaccine be administered immediately following preparation (withdrawal of the vial or ampoule contents into a syringe). This is the manufacturer's recommended practice for the preparation of MeNZB™ vaccine.

The fill volume for MeNZB™ vaccine is 0.6ml (required dose is 0.5ml), allowing 0.1ml for residuals remaining in the vial, syringe and needle. The manufacturer's advice is to withdraw the vaccine using a standard (= sharp) 21G 40 mm needle, keeping the vial in an upright position and tilting it at the end of the withdrawal in order to recover all the liquid from the bottom and side of the vial.

The Ministry of Health advises that the following requirements will need to be incorporated into the preparation process where significant numbers of MeNZB™ vaccine doses are to be prepared ahead of time.

- I. In addition to normal injection preparation practices (including aseptic technique hand hygiene prior to vaccine preparation commencing) it is advised that the persons preparing MeNZB™ vaccine should wash their hands or apply (use) a topical hand cleanser after every ten doses (one box) of vaccine prepared.
- II. There must be a new drawing up needle for each MeNZB™ vial.
- III. Prepared MeNZB™ vaccine should be used within the shortest possible time but must be used within 4 hours.
- IV. Prepared MeNZB™ vaccine must be stored between 2°C and 8°C and protected from exposure to light.

WHAT IS THE SHELF LIFE OF MeNZB™ VACCINE?

All MeNZB™ vials and boxes will be marked with an expiry date. Providing MeNZB™ vaccine is stored between 2°C and 8°C, the vaccine can be used up to and on the expiry date shown. In the event an expired vaccine is administered, this should be considered an invalid dose and the dose should be repeated. The repeat dose should be given at the appropriate interval after the last valid dose.

HOW AND WHERE SHOULD MeNZB™ VACCINE BE ADMINISTERED?

MeNZB™ will be administered by deep intramuscular injection in the:

- vastus lateralis muscle in infants aged under 12 months
- deltoid muscle or vastus lateralis in young children aged over 12 months. Vaccinators to use their professional judgement to make this decision (for further information see the New Zealand Immunisation Handbook 2002 pages 38 and 41)
- deltoid muscle of the non-dominant arm in older children and young people.

MeNZB™ vaccine can be administered at the same time as other vaccines provided it is administered using a separate syringe and at a different site. Where two intramuscular vaccines must be administered in a single limb for infants or young children, the vastus lateralis is the preferred site because the greater muscle mass allows for the injections to be appropriately spaced, ie, the injections should be separated by approximately 2cm.

If MeNZB™ vaccine is administered at the same time as other National Childhood Immunisation Schedule vaccines, ie, three injections are required, then MeNZB™ vaccine should be administered in one limb and the childhood vaccines in the other limb.

Refer to pages 37 to 44 of the Immunisation Handbook 2002 for information on vaccine administration, eg, intramuscular injection sites, needle length and needle angle, and pages 285 to 286 for information regarding safe injection practices, eg, drawing up from vials and changing needles.

WHAT IS THE PROCESS FOR REPORTING MeNZB™ VACCINE ADVERSE EVENTS TO CARM?

As with any other immunisations, vaccinators and health professionals should report any serious or unexpected AEFI occurring on the day of or subsequent to MeNZB™ immunisation, as notified by parents, caregivers or the young people, regardless of whether or not the health professional considers the event to have been caused by the immunisation. (Refer Table 2.4, page 51 of the Immunisation Handbook, 2002 and the section on 'Will MeNZB™ cause reactions', on page 14 of this document).

Using the standard CARM form (H1574) , MeNZB™ vaccine AEFIs should be reported to:

The Medical Assessor

Centre for Adverse Reaction Monitoring (CARM)
PO Box 913 (Freepost no. 112002)
Dunedin

Phone 03 479 7185 (Reception)

Phone 03 479 7247 (Dr Michael Tatley, Medical Assessor)

Information should include:

- age of vaccinee if identifiable information is declined
- date the MeNZB™ vaccine was administered
- MeNZB™ vaccine dose 1, 2 or 3
- MeNZB™ vaccine batch number and expiry date
- site the MeNZB™ vaccine was administered
- type and duration of adverse event
- treatment required.

5.0 MeNZB™ VACCINE COLD CHAIN MANAGEMENT AND ORDERING

The success of an immunisation programme is dependent on the maintenance of vaccine potency. To achieve this, the recommended temperature (between 2°C and 8°C) must be maintained during storage and distribution to avoid cumulative irreversible loss of potency due to exposure to heat or freezing.

It is especially important that the cold chain is maintained during the Meningococcal B Immunisation Programme as, unlike the National Immunisation Programme vaccines for which there usually is worldwide availability, MeNZB™ vaccine supplies are limited due to it being made specifically for New Zealand's epidemic, ie, it is a 'tailor-made' vaccine.

Major cold chain failures or high levels of MeNZB™ vaccine wastage could lead to a MeNZB™ vaccine shortage and prevent children and young people from being immunised.

HOW SHOULD MeNZB™ VACCINE BE STORED?

- MeNZB™ vaccine should be stored between 2°C and 8°C (refrigerated).
- MeNZB™ is freeze sensitive and must NOT be frozen.
- MeNZB™ vaccine must be protected from light.

Freezing of MeNZB™ vaccine will disrupt both the adjuvant and the vesicles, thereby inactivating the vaccine.

Providers with vaccine storage space or refrigerator performance problems should discuss this with the Local Immunisation Co-ordinator/District Immunisation Facilitator, as he/she will be able to give advice with regard to managing such situations.

HOW SHOULD PROVIDERS MANAGE THE ADDITIONAL DEMANDS ON VACCINE STORAGE ONCE MeNZB™ VACCINE BECOMES AVAILABLE?

For the National Immunisation Schedule vaccines distributed by ProPharma (Zuellig Pharma), providers are entitled to two orders per delivery address (provider) per month (not two orders per individual general practitioner within a practice), eg, Main Street Medical Centre, not individual general practitioners within the practice.

The increased demands on refrigerator capacity once the Meningococcal B Immunisation Programme commences will be substantial, especially during the influenza season.

To assist providers to manage their vaccine storage capacity during the programme, the Ministry is funding the MeNZB™ vaccine distributor for increased (but not unlimited) MeNZB™ vaccine deliveries per provider (delivery address).

Providers need to note that MeNZB™ vaccine deliveries will be limited to a maximum of one per day per delivery address, irrespective of the number of providers or practices working out of the address.

The Ministry is also implementing an allocation system to monitor the limited supply of MeNZB™ vaccine. The amount of MeNZB™ vaccine allocated to providers will be based on provider populations where known, and or usage of the National Immunisation Schedule vaccines.

Providers will need to do the following to manage vaccine storage capacity and maintain the cold chain.

1. Have the refrigerator thermostat set so that the refrigerator temperature sits at or about 5°C. This will allow for cyclical fluctuations of $\pm 3^{\circ}\text{C}$, ie, down to 2°C and up to 8°C, without compromising vaccines.
2. Work together in practices where there are multiple GPs or providers working out of the same address, to co-ordinate ordering of MeNZB™ vaccine for the combined (total) under 5 years and out of school population.
3. Ensure stocks of MeNZB™ vaccine are ordered in time and in the refrigerator, before commencing clinics.
4. Hold **no more than one week's supply of MeNZB™ vaccine at any given time** and spread the weekly requirement over 2 – 3 deliveries per week (or more if necessary).
5. Manage the supply of National Immunisation Schedule vaccines during the programme by:
 - utilising (taking up) the two ProPharma deliveries per month entitlement for National Immunisation Schedule vaccines
 - ordering only the quantity of National Immunisation Schedule vaccines required for the period until the next planned order.

WHO WILL BE DISTRIBUTING MeNZB™ VACCINE?

The Ministry of Health's MeNZB™ vaccine distributor is Exel New Zealand Limited.

The Exel contact details are:

Exel Airport 2

Cnr Manu Tapu Drive & Joseph Hammond Place
Auckland Airport, Mangere.

MeNZB™ Vaccine Order Supervisor: Nawal Singh, 021 393 571

MeNZB™ Vaccine Order Fax Number: 09 255 1980

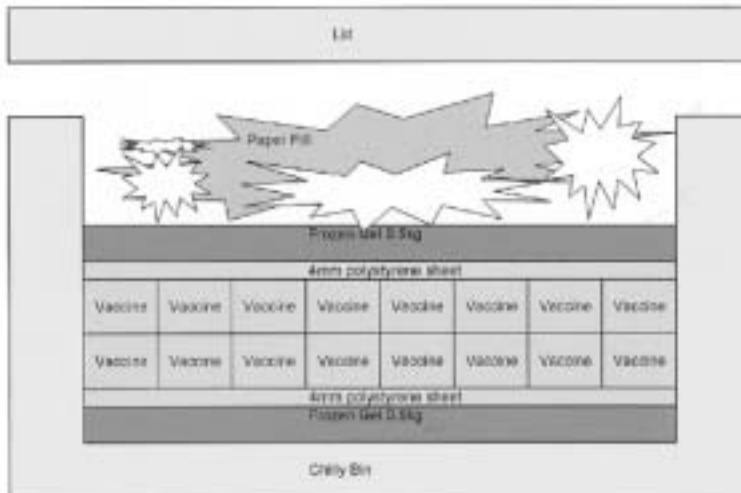
Customer Services Number: 09 255 1979

Exel will provide a customer service function between the hours of 8.30am and 4.30pm daily (Monday to Friday), to answer provider queries with regard to vaccine orders and returns only. MeNZB™ vaccine technical queries should be directed, in the first instance, to the Local Immunisation Co-ordinator or District Immunisation Facilitator, or if unavailable, the Meningococcal B Immunisation Programme Information Line – 0800 20 30 90 or the Meningococcal B Immunisation Programme Vaccine Co-ordinator.

HOW WILL MeNZB™ BE DELIVERED?

All MeNZB™ vaccine orders (whether for same day or overnight delivery) will arrive in chilly bins, and will be delivered by Courier Post. This is different from the National Immunisation Programme vaccine deliveries where same day deliveries arrive in a cardboard box. The schematic diagram shows how the chilly bin will be packed.

FIGURE 3



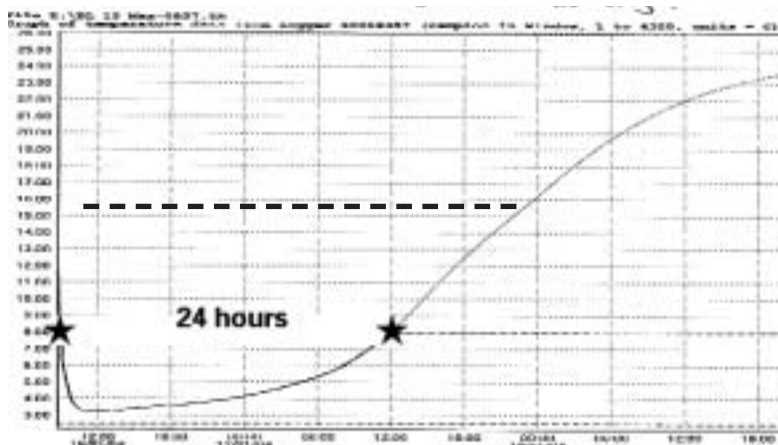
Exel New Zealand Limited Chillybin BL15

(Note: the paper fill will be scrunched up butcher paper, not shredded paper)

In the event a MeNZB™ vaccine delivery does not arrive within 24 hours, the Cold Chain Coordinator should contact the Exel MeNZB™ Vaccine Order Supervisor: Nawal Singh, phone 09 255 1982 or 021 393 571, for instructions.

The specially made chilly bin and the ice packs and packing method being used for MeNZB™ vaccine deliveries has been extensively trialled and independently validated as maintaining vaccine temperature between 2°C and 8°C for 24 hours duration at all times during the vaccine transportation (delivery) process. For the national immunisation schedule vaccines delivered by ProPharma, deliveries have to occur within a 4-6 hour window. **This is not the case with the MeNZB™ vaccine deliveries.** MeNZB™ vaccine deliveries have 24 hours from the time the chilly bin (order) was packed, for delivery to occur.

FIGURE 4



Temprecord (electronic temperature data logger) confirming temperature maintenance between 2°C and 8°C for 24 hours duration from the time the chilly bin was packed.

HOW DO PROVIDERS ORDER MENZB™ VACCINE?

1. MeNZB™ vaccine orders will only be accepted and deliveries made one week before the programme commences in a DHB area, eg, if the DHB start date for commencing vaccinating is 19 July, then providers will only be able to start ordering and receiving vaccine from 12 July.
2. Orders cannot be placed in advance / ahead (eg. provider places an order 20 July but wants delivery on 27 July). Orders will be processed as they are received. This is because of the high volume of orders associated with this programme.
3. Providers may order MeNZB™ vaccine as required. However to manage vaccine supply and avoid duplication of orders, only one order per delivery address a day will be accepted.
4. Orders must be made on Ministry / Exel order form (See Appendix 4). A master copy of the order form has been included in this pack for photocopying.
It is recommended that providers:
 - complete the provider name, physical delivery address, contact person, phone number, fax number and hours open to accept and sign for deliveries on the MeNZB™ vaccine order form master copy, before photocopying. This will ensure the correct details are provided and save time when placing orders, as only the order date, order quantity and signature will need to be completed.
5. Orders will only be received by fax. No telephone orders will be accepted.
It is recommended that providers:
 - set up the fax machine to print a fax confirmation slip, so that you know the fax (order) has gone through satisfactorily.
6. Orders must be placed in multiples of 10 doses, eg, 20 doses, 50 doses, 200 doses.
7. For primary care providers, the minimum order is 20 doses and the maximum single order is 240 doses (for large practices only).
8. Providers must sign for each vaccine order delivered.

WHEN CAN PROVIDERS EXPECT MeNZB™ VACCINE ORDERS TO BE DELIVERED?

MeNZB™ vaccine will be delivered Monday through to Friday only. The day of the week and the time the order is placed will determine when the order will be delivered (See Appendix 4).

Same day deliveries will only be available in Auckland and Christchurch. For all other areas, orders must be placed by 2pm for next day (overnight) delivery to occur. Orders received after 2pm will be processed the next day with delivery occurring the following day. For example, orders received after 2pm Wednesday will not be processed until Thursday with delivery occurring on Friday.

Providers on overnight deliveries will not receive deliveries on Mondays, due to courier service operations vaccine cannot be dispatched on Saturdays or Sundays.

On receipt of MeNZB™ vaccine orders the provider:

- should check the chilly bin contents against the order form (the number of doses ordered should match the number of doses delivered)
- must sign for (courier receipt) every MeNZB™ vaccine delivery (date and time).

Providers should retain and file all MeNZB™ vaccine orders packing slips.

WHAT ACTION SHOULD PROVIDERS TAKE IN SITUATIONS WHERE MeNZB™ HAS BEEN EXPOSED TO TEMPERATURES OUTSIDE OF 2°C AND 8°C ?

The MeNZB™ vaccine should be stored between 2°C to 8°C at all times.

Situations where MeNZB™ vaccine may have or has been exposed to temperatures below 2°C or above 8°C should be discussed with the Local Immunisation Co-ordinator / District Immunisation Facilitator (or if unavailable, the Meningococcal B Immunisation Programme Vaccine Co-ordinator) prior to any vaccine being discarded.

WHAT SHOULD PROVIDERS DO IN THE EVENT THAT A MeNZB™ VACCINE DELIVERY ARRIVES AND THERE IS INSUFFICIENT STORAGE SPACE IN THE REFRIGERATOR?

By careful use of vaccine storage space, rapid turnover of all vaccine stock and frequent deliveries, it should be possible for providers to keep all vaccines stored between 2°C and 8°C (refrigerated).

However, if a provider temporarily finds themselves with insufficient storage space, when a MeNZB™ vaccine delivery arrives it could be left sealed in the chilly bin, for up to but not exceeding 24 hours from when the vaccine was packed (date and time of packing will be on the chilly bin label), providing the chilly bin is stored in a cool area, ie, away direct sunlight and heat sources.

In the above situation, the provider would have to sign for the delivery without opening the chilly bin to check the number of doses ordered matches the number of doses delivered.

As soon as storage space allows, the vaccine should be transferred to the refrigerator.

CAN SURPLUS MeNZB™ VACCINE BE RETURNED TO EXEL?

No, once the provider has accepted a MeNZB™ vaccine delivery, it cannot be returned to Exel for redistribution. All returned MeNZB™ vaccine has to be destroyed. This is because neither Exel nor the Ministry can guarantee the vaccine has been stored between 2°C to 8°C during the intervening period.

HOW DO PROVIDERS RETURN COMPROMISED MeNZB™ VACCINE TO EXEL?

Once it is confirmed that MeNZB™ vaccine has been compromised, the provider should call Exel Customer Services (09 255 1979) who will fax a return authorisation form and arrange for a courier to uplift the vaccine.

The compromised MeNZB™ vaccine (no other vaccine) should be placed into a suitable sturdy plastic container or one of the delivery chilly bins and clearly labelled 'MeNZB™ Vaccine For Destruction'.

WHAT DO PROVIDERS DO WITH THE CHILLY BINS IN WHICH MeNZB™ IS DELIVERED?

Exel cannot recycle the chilly bins as they have been outside the company's quality assurance controls. However where possible, the chilly bins should be disposed of in a thoughtful (environmentally friendly) way.

6.0 OTHER COMMONLY ASKED QUESTIONS

WHY IS MeNZB™ IMMUNISATION ONLY AVAILABLE FOR THOSE UP TO 20 YEARS OF AGE?

While meningococcal disease can affect anyone, children and young people are disproportionately affected, with more than 80% of cases occurring in those under 20 years, hence the programme is targeting all those aged 0 – 19 years.

It is not possible to purchase MeNZB™ vaccine for any other age group at this stage. This is because there is a limited amount of vaccine and the programme aims to protect those who are at greatest risk from meningococcal B disease first.

The Meningococcal B Immunisation Programme Eligibility Policy can be found in Appendix 2.

DO PROVIDERS NEED TO CHANGE THEIR IMMUNISATION CONSENT PROCESS FOR MeNZB™ IMMUNISATION?

As with all other immunisations (refer P33 Immunisation Handbook, 2002), health professionals should offer information regarding meningococcal disease and MeNZB™ vaccine. Parents, guardians and young people should not have to ask for information. The depth of information required will differ, but the minimum will ensure that the parent, caregiver or young person understands what the vaccine is for and the possible side effects.

As per all other immunisation programmes, consent is required for each episode or dose. Parents, guardians or young people have the right to change their mind, and may withdraw consent at any time. This should be recorded on the personal health record.

The Code of Health and Disability Consumers' Rights (1996) does not require written consent by a parent or guardian where a child is presented for immunisation and the parent is present. Verbal consent is sufficient if the parent or guardian consents in person, having been fully informed about the procedure.

Where consent is obtained formally but not in writing, it is good practice to record what was discussed, when the discussion took place, and that consent was obtained.

To assist providers inform parents, guardians and young people about meningococcal B disease etc, the following resources have been developed and are being translated into Māori, Samoan, Tongan, Cook Island Maori, Tuvaluan, Tokelauan, Niuean, Fijian, Korean, Vietnamese, Chinese, Arabic, Hindi.

- an information leaflet
- a post-vaccination information sheet
- posters on the programme (in Māori, Samoan and Tongan only)

Other resources (produced in English only) include:

- a booklet about the programme
- a flip chart to assist with obtaining consent
- a Well Child / Tamariki Ora Book sticker
- three stickers for young children, one to be given after each injection.

CAN THE MeNZB™ VACCINE BE GIVEN AT THE SAME TIME AS OTHER VACCINES?

As MeNZB™ is an inactivated vaccine it can be administered at the same time as other vaccines provided it is administered using a separate syringe and at a different site.

National Immunisation Schedule vaccines administered at the same time as MeNZB™ vaccine are claimed as a separate immunisation event.

HOW DO PROVIDERS RECORD MeNZB™ IMMUNISATION EVENTS?

When an individual receives or declines to receive MeNZB™ immunisation, this information is recorded in the individual's personal health record as well as being sent to the National Immunisation Register (NIR).

- If the process is electronic, and the provider is using the NIR compatible version of the following PMS systems (Medtech32, Next Generation, Houston VIP, MedCen, Profile for Windows), then the provider records the MeNZB™ immunisation event data in the Patient Management System (PMS) and it is automatically transferred through to the NIR, when the provider dials up (is connected) to do their Healthlink messaging.
- If the process is manual, ie, the provider is not using one of the above named PMS systems, then the provider completes the Meningococcal B Immunisation Event form (NIR3M) and faxes or couriers it to the DHB NIR Administrator. It is important that this information is recorded on the NIR within the required timeframe. Locally agreed protocols for sending this information to the NIR should be followed.
- Vaccination data for MeNZB™ must be loaded onto the National Immunisation Register (NIR), via any process, within 24 hours of the vaccination being administered in the Counties-Manukau, Auckland, Waitemata and Northland District Health Board areas. Exceptions (no more than 5%) may take 48 hours.

For all other DHBs the MeNZB™ vaccination data must be loaded on to the NIR within 72 hours, or 96 hours for exceptions (no more than 5%).

HOW DO PROVIDERS CLAIM MeNZB™ IMMUNISATION EVENTS?

- If the process is electronic, the provider makes the claim electronically using Practice Management Systems.
- If the process is manual, the provider uses the manual form (Meningococcal B Immunisation Event Form NIR3M) available from Wickliffe on 0800 259 138. The provider HealthPAC payee number should be quoted.

NHI Requirements

The patient's National Health Index (NHI) number needs to be included on all claim forms. The MeNZB™ immunisation claims require a minimum of 85% of the claim (patient's names) to be submitted with a valid NHI Number. Where the claim does not comply with the 85% threshold payment will only be made for the patients where a valid NHI number is provided.

Note: NHI numbers are also required for entry of immunisation data on to the NIR, for each event or record entered.

WHO DO PROVIDERS CONTACT FOR MORE INFORMATION ON MeNZB™ IMMUNISATION OR THE NIR?

- The District Health Board Meningococcal B Immunisation Programme Project Manager.
- The Local Immunisation Co-ordinator or District Immunisation Facilitator.
- The Meningococcal B Immunisation Programme website www.immunise.moh.govt.nz
- The Meningococcal B Immunisation Programme Information Line freephone 0800 20 30 90.
- The DHB NIR Administrator.

HOW DOES BRIDGING CLINICAL TRIAL DATA FROM OTHER VACCINES APPLY TO MeNZB™?

Each part of a clinical trial is designed to answer questions about a new product that are either unknown or require clarification. The use of bridging information – or designing bridging trials, to obtain this information – is a standard process to help test a single hypothesis or set of hypotheses about a new product that is closely related to an original or 'parent' product. For vaccine clinical trials, this information can help determine issues such as dose numbers, interval between doses, dose strength, age groups involved in a clinical study programme, number of participants to power a study and provides background knowledge on the likely safety profile of a new vaccine involved in a research programme. This can be demonstrated through use of the original/'parent' or comparable vaccine acting as a control arm of a study, or as a stand alone bridging study in a new location. This allows assessment of the hypothesis that the results of two products are comparable and that this bridging data can act as a supporting body of knowledge of a product's performance when assessed under similar conditions.

The design of the New Zealand MeNZB™ clinical trials was heavily influenced by existing information that was available on the parent MenBVac™ vaccine, developed by the Norwegian Institute of Public Health, and other similar group B meningococcal vaccines using the same outer membrane vesicle (OMV) technology. While the MenBVac™ vaccine targeted a different antigen to the New Zealand epidemic strain, the MeNZB™ vaccine was manufactured using the same technology and ingredients and was used as a control arm in the Phase I/II MeNZB™ clinical studies. The information pertaining to the safety profile of the MenBVac™ vaccine and the MeNZB™ clinical trials was sent to Medsafe for assessment as part of the overall licensure process.

7.0 THE NATIONAL IMMUNISATION REGISTER (NIR)

WHAT IS THE NIR?

The National Immunisation Register (NIR) is a computerised information system that has been developed to hold immunisation details of New Zealand children. The NIR will record all immunisations given as part of the Meningococcal B Immunisation Programme. This will enable safety and coverage monitoring of the MeNZB™ vaccine.

The NIR is a key tool that will assist New Zealand to improve its immunisation rates. Improved immunisation coverage will offer individual protection against vaccine-preventable diseases and protection for the community against recurring epidemics.

The NIR will enable authorised health professionals to quickly and easily find out what vaccines a child has been given.

This will include children whose families have shifted to another area or changed healthcare providers. This will help to make sure immunisations are given at the appropriate time. The NIR will also provide an accurate record of immunisation coverage rates for the National Childhood Immunisation Schedule vaccines and for the Meningococcal B Immunisation Programme. This will enable better programme planning to target populations with the lowest immunisation rates.

For the NIR to meet the requirements of the Privacy Act 1993 and the Health Information Privacy Code 1994 (Rule 3), providers will need to ensure that the individual (or their parent/guardian) is well informed about the NIR, its purpose, the benefits that registration will bring to the individual and the community, the data that will be collected, and how it will be used.

WHAT INFORMATION WILL BE HELD ON THE NIR?

The NIR will collect the following information for all those receiving MeNZB™ vaccine or who decline the vaccine: the individual's name, address, date of birth, gender, NHI number and ethnicity; parent/guardian details and contact information; nominated health professionals (GP and Well Child provider) and immunisations given.

If an individual (or their parent/guardian) consents to be vaccinated with MeNZB™ it is mandatory that this information is collected on the NIR. This is because MeNZB™ licensure requires all MeNZB™ immunisations to be recorded on the NIR for safety monitoring purposes.

If MeNZB™ immunisation is declined, an individual can opt-off the collection of this information on the NIR, in which case only their date of birth, NHI number, DHB they are resident in, date of opting off and any immunisation given up to this date will be recorded.

For more information on opting off the collection of information on the NIR please refer to the NIR Manual for Vaccinators or contact your local DHB NIR Administrator.

HOW WILL INFORMATION FROM GPS BE TRANSFERRED TO THE NIR?

GPs and other vaccination providers with an electronic Patient Management System (PMS) will have the capacity to link into the NIR. Providers without electronic systems will use paper-based systems to provide data. Immunisation information will then be transferred to the NIR. Providers will be able to access the NIR through their existing PMS or by contacting the DHB NIR Administrator to help manage their immunisation services.

CAN PARENTS / GUARDIANS ACCESS THE INFORMATION HELD ON THE NIR ABOUT THEIR CHILD?

Individuals (or their parents and guardians) will be able to access their (or their child's) immunisation information or request for that information to be corrected through their health care provider.

HOW LONG WILL THE INFORMATION BE RETAINED?

The information on the NIR will be retained for an individual's lifetime, plus a period of 10 years.

HOW DO I GET LINKED UP TO THE NIR?

The NIR Project Managers in each DHB will be offering NIR training to local providers closer to the NIR 'go live' date for each DHB.

NIR training packages and manuals have been developed to assist providers in the use of the NIR.

Further information on the NIR can be found on the Ministry of Health website www.moh.govt.nz/nir.

APPENDIX ONE: THE NATIONWIDE PROGRAMME PLAN

Approximate launch dates for the nationwide programme (subject to confirmation) are presented in the table below.

DISTRICT HEALTH BOARD	PRIMARY CARE			SCHOOLS
	Primary Care 6mth – 19yr	Primary Care 6wk – 5mth	Young people no longer at school (approx. 17–20 years)	
Counties Manukau Eastern Auckland	19 July 2004	3 February 2005	March 2005	2 August 2004
Waitemata	2 December 2004	3 February 2005	March 2005	17 March 2005
Auckland	8 December 2004	3 February 2005	March 2005	21 March 2005
Northland	22 November 2004	TBA – see note	May 2005	2 May 2005
Waikato	31 January 2005	TBA – see note	March 2005	21 March 2005
Bay of Plenty	7 February 2005	TBA – see note	May 2005	2 May 2005
Lakes	7 February 2005	TBA – see note	May 2005	2 May 2005
Tairāwhiti	14 February 2005	TBA – see note	April 2005	4 April 2005
Taranaki	15 March 2005	TBA – see note	May 2005	9 May 2005
Hawke's Bay	21 March 2005	TBA – see note	April 2005	4 April 2005
Whanganui	4 April 2005	TBA – see note	May 2005	9 May 2005
Mid Central	18 April 2005	TBA – see note	May 2005	9 May 2005
Hutt Valley	2 May 2004	TBA – see note	May 2005	16 May 2005
Capital and Coast	9 May 2005	TBA – see note	May 2005	16 May 2005
Wairarapa	23 May 2005	TBA – see note	May 2005	23 May 2005
Otago	30 May 2005	TBA – see note	May 2005	30 May 2005
Southland	6 June 2005	TBA – see note	May 2005	30 May 2005
South Canterbury	13 June 2005	TBA – see note	June 2005	6 June 2005
Canterbury	20 June 2005	TBA – see note	June 2005	13 June 2005
West Coast	27 June 2005	TBA – see note	June 2005	6 June 2005
Nelson Marlborough	4 July 2005	TBA – see note	June 2005	13 June 2005

NOTE: On 3 February 2005, the minimum age MENZB™ is licensed for was reduced to six weeks. Initially, only infants aged over 6 weeks in the Auckland, Waitemata and Counties Manukau DHBs are eligible for MENZB™ vaccine. It is expected that infants aged over 6 weeks elsewhere in New Zealand will become eligible in May 2005.

Please refer to the addendum on pages 39 and 40 for details. If in doubt about eligibility, please call 0800 20 30 90 toll free.

APPENDIX TWO: THE MENINGOCOCCAL B IMMUNISATION PROGRAMME ELIGIBILITY POLICY

The Meningococcal B Immunisation Programme (the 'programme') service delivery models:

1. Primary care providers to immunise infants and young children from age 6 weeks¹ to school age.
2. Public health nursing services to immunise students in primary, intermediate and secondary education.
3. A range of providers such as general practices, Māori and Pacific primary care providers, workplace and occupational health providers, university student health services to immunise teenage school leavers / out of school young people up to but not including 20 years of age².
4. District Health Board (DHB) approved Outreach Immunisation Service providers to immunise at various locations:
 - tamariki and rangatahi Māori
 - Pacific children and young people
 - children and young people living in more deprived areas (NZ Dep Index 9 or 10) aged from six months up to 20 years of age¹.

Responsibility for the child or young person completing (and being offered the opportunity to complete) the MeNZB^{TM3} course remains with the initial provider, unless there is a formal transfer (written) to another provider, eg, primary care provider to Outreach Immunisation Services, public health nursing services to a primary care provider or Outreach Immunisation Services.

Providers are encouraged to find children and young people, especially those most at risk of the disease, who are not enrolled and encourage them to enroll to be immunised.

Vaccine supply constraints and the mass nature of the programme have required the development of the following eligibility policy.

1. PROGRAMME ELIGIBILITY

- 1.1 The programme is for infants, children and young people aged from six weeks up to 20 years of age¹.

A young person is still eligible to receive MeNZBTM vaccine if they are 20 years of age or over, as long as their first dose was given when they were under 20 years of age and the immunisation date of service is within the national programme timeframe.

1 On July 8, 2004, MENZBTM vaccine was licensed for use in children six months and older. On 3 February 2005, the minimum age MENZBTM is licensed for was reduced to six weeks. Initially, only infants aged over 6 weeks in the Auckland, Waitemata and Counties Manukau DHBs are eligible for MENZBTM vaccine. Please refer to the addendum on pages 39 and 40 for details. If in doubt about eligibility, please call 0800 20 30 90 toll free.

2 A young person is still eligible to receive MeNZBTM vaccine if they are 20 years of age or over, as long as their first dose was given when they were under 20 years of age and the immunisation date of service is within the national programme timeframe.

3 MeNZBTM means the New Zealand group B meningococcal vaccine manufactured and trademarked worldwide by Chiron Vaccines (a division of Chiron Corporation).

1.2 The immunisation information of children and young people receiving MeNZB™ vaccine must be entered on the National Immunisation Register (NIR), either automatically or manually in the required timeframe. Children and young people who do not wish to have their information entered into the NIR will not be eligible for MeNZB™ immunisation. This is because MeNZB™ licensure requires all MeNZB™ immunisations to be recorded on the NIR, for safety monitoring purposes.

2. RESIDENTIAL ELIGIBILITY

Different District Health Board (DHB) populations will become eligible as the programme moves through the country. In some cases children and young people will live in one DHB while their usual provider is based in another.

The eligibility rules:

- 2.1 Children and young people who are enrolled at a school in an eligible DHB area but live in a different DHB area, will be eligible.
- 2.2 Children and young people who live in an eligible DHB area but are enrolled at a school in a different DHB area, will not be eligible.
- 2.3 Children under five years and young people who are no longer at school and are enrolled with a provider based in an eligible DHB area but live in a different DHB area, will be eligible.
- 2.4 Children under 5 years and young people who are no longer at school and live in an eligible DHB area but are enrolled with a provider not based in an eligible DHB area, will not be eligible.
- 2.5 Children under 5 years and young people who are no longer at school and live in an eligible DHB area but are not enrolled with a provider, should be encouraged to enroll with a local provider and be immunised.
- 2.6 Children and young people who live in an eligible DHB area and are referred (by a provider based in an eligible DHB area) to a DHB approved Outreach Immunisation Service in an eligible DHB area, will be eligible.

3. IMMUNISATION BY PRIMARY CARE PROVIDERS, OF SCHOOL-AGED CHILDREN AND YOUNG PEOPLE IN PRIMARY, INTERMEDIATE AND SECONDARY EDUCATION.

Primary care providers have agreed to support the programme for children and young people enrolled in schools, by referral to the school-based campaign. Children and young people who are school-aged and attending primary, intermediate and secondary school, should be immunised by public health nurse services at school, unless they meet one of the criteria listed below (3.1 – 3.5). In all instances immunisation of these children and young people by primary care provider, will not be able to take place until the school-based campaign commences within that DHB area.

The criteria for not being immunised:

- 3.1 The child or young person has a bleeding disorder.
- 3.2 The child or young person has a documented history of anaphylaxis with cardio respiratory symptoms.
- 3.3 The child or young person has a documented history of worsening episodes of allergic symptoms due to any cause.

3.4 The school-based campaign has been completed and the child or young person has been 'missed'.

3.5 The child or young person has had a MeNZB™ dose in the school-based campaign but has since left school (as per 6.1 below).

4. IMMUNISATION BY PRIMARY CARE PROVIDERS OF SCHOOL AGED CHILDREN AND YOUNG PEOPLE NOT IN PRIMARY, INTERMEDIATE AND SECONDARY EDUCATION.

4.1 Home-schooled and correspondence school children and young people will have the option of:

- accessing the school-based campaign within the area in which they live in accordance with the DHB policy
- being immunised by their usual primary care provider, once the school-based campaign commences within the DHB area where that provider is situated.

5. CHILDREN WHO COMMENCE THEIR MeNZB™ IMMUNISATION COURSE WITH A PRIMARY CARE PROVIDER AND TURN FIVE YEARS OF AGE BEFORE THE COURSE IS COMPLETED.

5.1 Children who commence their MeNZB™ immunisation course with a primary care provider should complete it in primary care.

6. YOUNG PEOPLE WHO COMMENCE THEIR MeNZB™ IMMUNISATION COURSE IN THE SCHOOL-BASED CAMPAIGN AND LEAVE SCHOOL BEFORE THE COURSE IS COMPLETED.

6.1 Young people who commence their MeNZB™ immunisation course in the school-based campaign will have the option of:

- accessing the school-based campaign for their remaining doses
- being immunised by their usual primary care provider
- being immunised at a tertiary education institution.

7. CHILDREN AND YOUNG PEOPLE WHO COMMENCE THEIR MeNZB™ IMMUNISATION COURSE IN ONE AREA, BUT BEFORE THE COURSE IS COMPLETED MOVE TO AN AREA WHERE PROGRAMME DELIVERY HAS NOT YET COMMENCED.

7.1 If it is known the child or young person will be shifting from the area, the provider should attempt to administer two doses prior to the move, ie, the second dose can be moved forward to four weeks from the first if necessary. The third dose would then be due once primary care provider delivery commenced within the area they were shifting to. A delay to the third dose is not as critical as a delay to the second.

7.2 Vaccine will not be transported to a DHB before that DHB is eligible for vaccine.

8. CHILDREN AND YOUNG PEOPLE WHO ARE VISITORS, FOREIGN OR FEE-PAYING STUDENTS WHO ARE IN THE NEW ZEALAND FOR SHORT-TERM PERIODS.

It is only after the completion of the third dose of MeNZB™ vaccine that the anticipated level of protection will be conferred. It will take approximately four months to deliver a course of MeNZB™ vaccine.

8.1 Children and young people who:

- are visitors, foreign or fee-paying students
- will remain in New Zealand continuously for a period that equals or exceeds six months
- are enrolled with a provider based in an eligible DHB area but live in a different DHB area.

will be eligible for MeNZB™ immunisation.

8.2 Children and young people who:

- are visitors, foreign or fee-paying students
- will remain in New Zealand continuously for a period that equals or exceeds six months
- live in an eligible DHB area but are enrolled with a provider not based in an eligible DHB area

will not be eligible unless they attend (as a casual patient) a provider in an eligible DHB area.

APPENDIX THREE: SUMMARY INFORMATION ON THE FREQUENCY OF REPORTED REACTIONS ACROSS THE CLINICAL TRIALS

- Key message 1:** Most toddlers, children and young people can expect to have a mild to moderate injection site reaction.
- Key message 2:** Injection site reactions may include pain or tenderness, temporary redness, swelling or induration (the hardening of normally soft tissue, especially the skin, because of inflammation).
- Key message 3:** Injection site reactions usually last 2 – 3 days, but in a few cases may last longer. All injection site reactions will completely resolve.
- Key message 4:** A reaction to one dose does not mean there will be the same reaction to other doses, but it does increase the chance of a similar reaction occurring.
- Key message 5:** Severe reactions of any type are uncommon and to date there is no evidence from the clinical trials that long-term reactions occur.

PERCENTAGE OF LOCAL REACTIONS OVER ALL DOSES OF MeNZB™ GIVEN DURING THE CLINICAL TRIALS				
Type of reaction	Age range and number of doses			
	6-8 Months 700 doses	16-24 Months 772 doses	8-12 Years 1606 doses	Adults (>18 years) 173 doses
Erythema:				
Any	33%	55%	11%	24%
Mild	20%	15%	7%	17%
Moderate	11%	35%	3%	3%
Severe	1%	5%	1%	4%
Induration:				
Any	43%	58%	10%	23%
Mild	26%	32%	6%	13%
Moderate	16%	25%	3%	8%
Severe	1%	2%	1%	2%
Swelling:				
Any	15%	34%	7%	20%
Mild	8%	16%	3%	5%
Moderate	5%	16%	2%	7%
Severe	2%	2%	1%	8%
Pain¹:				
Any	N.A.	N.A.	78%	96%
Mild			42%	51%
Moderate			30%	42%
Severe			7%	3%
Tenderness²:				
Any	37%	73%	N.A.	N.A.
Minor light reaction to touch	23%	33%		
Cried or protested to touch	11%	25%		
Cried when injected limb was moved	3%	15%		

¹ Pain has been measured only in children 8-12 years old and adults

² Tenderness has been measured only in toddlers

PERCENTAGE OF SYSTEMIC REACTIONS OVER ALL DOSES OF MeNZB™ GIVEN DURING THE CLINICAL TRIALS				
Type of reaction	Age range and number of doses			
	6-8 Months 700 doses	16-24 Months 772 doses	8-12 Years 1606 doses	Adults (>18 years) 173 doses
Headache[^]:				
Any	N.A.	N.A.	23%	24%
Mild			16%	18%
Moderate			5%	6%
Severe			2%	0%
Malaise[^]:				
Any	N.A.	N.A.	18%	23%
Mild			11%	16%
Moderate			5%	8%
Severe			2%	0%
Nausea[^]:				
Any	N.A.	N.A.	9%	12%
Mild			6%	9%
Moderate			2%	2%
Severe			1%	0%
Myalgia[^]:				
Any	N.A.	N.A.	9%	25%
Mild			7%	16%
Moderate			2%	8%
Severe			1%	1%
Arthralgia[^]:				
Any	N.A.	N.A.	6%	4%
Mild			4%	4%
Moderate			1%	0%
Severe			<1%	0%
Irritability#:	49%	41%	N.A.	N.A.
Sleepiness#:	18%	19%	N.A.	N.A.
Change In Eating Habits`#:	23%	19%	N.A.	N.A.
Vomiting#:	11%	6%	N.A.	N.A.
Diarrhoea#:	11%	12%	N.A.	N.A.
Rash:				
Any	14%	8%	3%	N.A.
Other	14%	7%	4%	
Urticarial	<1%	1%	<1%	
Body Temperature:	15%	10%	3%	1%
Axillary >38.5°C in infants and toddlers				
Sub-lingual >38°C in children and adults				

[^] Nausea, Malaise, Myalgia, Arthralgia and Headache have been measured only in children and adults

Irritability, Sleepiness, Change in Eating Habits, Vomiting, Diarrhoea and Rash have not been measured in adults

APPENDIX FOUR: MeNZB™ VACCINE ORDER FORM, TIME OF ORDER PLACEMENT AND DELIVERY



MeNZB™ FAX ORDER FORM

FAX TO: 09 255 1980

ORDER INFORMATION

1. Do not stockpile (over order) vaccine.
2. Providers may order MeNZB™ vaccine as required. However to manage vaccine supply and avoid duplication of orders, only one order per delivery address (provider name*) a day will be accepted.
3. Orders must be made on this order form.
4. Orders will only be received by fax (as above). No telephone orders will be accepted.
5. Orders must be placed in multiples of 10 doses eg. 20 doses, 50 doses, 200 doses.
6. For primary care providers, the minimum order is 20 doses.
7. For public health nursing services, the minimum order is 200 doses.
8. The day of the week and the time the order is placed will determine when the order will be delivered (See over).
9. Providers must sign for each vaccine order delivered.

* Note: One order per provider (delivery address) per day eg. Main Street Medical Centre (not individual general practitioners within the practice) or DHB Public Health Nursing Services.

Please Complete All Fields below

Order Date _____

Quantity Ordered (Doses) _____

Provider Name _____

Physical Delivery Address _____

Contact Person _____

Phone Number _____ Fax Number _____

Hours the provider is open to accept and sign for deliveries. _____

Signature _____

Queries in regard to your MeNZB™ vaccine orders or returns should be directed to Exel Customer Services (09 255 1979), between the hours of 8.30am and 4.30pm daily (Monday to Friday). MeNZB™ vaccine technical queries should be directed to the Local Immunisation Coordinator or District Immunisation Facilitator (or, if unavailable, the Ministry's Meningococcal B Immunisation Programme Vaccine Coordinator).

Office Use Only

Date Received	Date Input	Input By	Order Number

Auckland – Orders Placed Monday to Thursday

Delivery Area	Order Placement	Delivered by
Auckland CBD*	By 08.30am	1.00pm the same day
Auckland CBD	By 12 midday	5.00pm the same day
Auckland CBD	After 12 midday	09.00am the following day

* CBD means from Albany / Browns Bay in the north, to Papakura in the south.

Auckland – Orders Placed on Friday

Auckland CBD	By 10.00am	5.00pm the same day
Auckland CBD	After 10.00am	1.00pm on Monday

Rest of the North Island – Orders Placed Monday to Thursday

Delivery Area	Order Placement	Delivered by
Other North Island	By 2.00pm (See footnote 1)	09.00am the following day

Rest of the North Island – Orders Placed on Friday

Delivery Area	Order Placement	Delivered by
Other North Island	By 2.00pm (See footnote 2)	09.00am on Tuesday

South Island**Christchurch – Orders Placed Monday to Thursday**

Delivery Area	Order Placement	Delivered by
Christchurch CBD*	By 08.30am	1.00pm the same day
Christchurch CBD	By 12 midday	5.00pm the same day
Christchurch CBD	After 12 midday	09.00am the following day

* Means from Belfast in the north, to Rolleston in the south.

Christchurch – Orders Placed on Friday

Christchurch CBD	By 10.00am	5.00pm the same day
Christchurch CBD	After 10.00am	1.00pm on Monday

Rest of the South Island – Orders Placed Monday to Thursday

Other South Island	By 2.00pm	09.00am the following day
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Rest of the South Island – Orders Placed on Friday

Delivery Area	Order Placement	Delivered by
Other South Island	By 2.00pm (See footnote 2)	09.00am on Tuesday

Footnotes:

- Orders received after 2pm will be processed the next day with delivery occurring the following day. For example, orders received after 2pm Wednesday will not be processed until Thursday with delivery occurring on Friday.
- For providers on overnight deliveries, there will not be any Monday deliveries, as vaccine cannot be dispatched on Saturday or Sunday due to courier service operations.

ADDENDUM

MeNZB™ VACCINATION FOR THOSE AGED 6 WEEKS TO 6 MONTHS

Medsafe has extended the licence for MeNZB™ to include infants aged 6 weeks and older. Initially, only vaccinators in the Counties Manukau, Auckland and Waitemata District Health Boards, where an intensive safety monitoring system is in place, can administer the MeNZB™ vaccine to infants 6 weeks of age and older. Vaccinators in other District Health Boards will be advised when they are authorised to administer the MeNZB™ vaccine to infants.

Clinical data submitted to Medsafe supports the concurrent administration of MeNZB™ with the routine schedule. All of those aged between 6 weeks and 6 months become eligible at the same time and, as a result, transitional or catch-up vaccine schedules are required. This document describes the recommended schedules.

Principles

The key principles for catch-up schedules are that:

- the interval between doses 1 and 2 of MeNZB™ should not be less than 4 weeks and the interval between doses 2 and 3 should not be less than 6 weeks
- it is important for children to get all routine immunisations. The routine schedule should not be delayed to accommodate MeNZB™ administration and MeNZB™ can be given at the same time as routine childhood immunisations.
- MeNZB™ should be administered in a different limb to the routine vaccines. The sites of the administration of two routine vaccines in the same limb should be at least 2cm apart.

Schedules

- The starting point for each schedule below is the age at which the child presents.
- If immunisation has not occurred on time, the routine schedule should be administered as soon as possible, ie: current practice. The schedule for MeNZB™ should be administered as described below, ensuring that the number of visits is minimised by administering it with the routine schedule vaccines as much as possible.
- If uncertain, it is better to err on the side of giving rather than not giving doses.
- It is never necessary to repeat prior doses; if the schedule is interrupted, simply resume the schedule as if doses had not been missed. A possible exception to this could occur if two doses are inadvertently administered less than four weeks apart – seek expert advice in this situation.
- If not administered simultaneously there is no minimum interval (ie: could be the next day) between the administration of MeNZB™ and the routine schedule vaccines. NB: none of the vaccines administered in the first 6 months of life are live attenuated vaccines.

Recall

All infants between 6 weeks and 6 months of age should be recalled for MeNZB™ vaccine doses. MeNZB™ and the routine schedule vaccines should be administered according to the age at which they present. See schedules below.

Pre-term infants and other infants with low birth weight should be immunised at the usual chronological age with the usual vaccine dosage as for other routine childhood vaccines (see Immunisation Handbook page 19). For infants still in hospital at 6 weeks of age, MeNZB™ should be administered concurrent with other routine childhood vaccines, whether given at 6 weeks of age or prior to discharge.

Children under 6 months, who have completed the routine immunisation schedule should be recalled and offered three doses of MeNZB™ at 6 weekly intervals commencing as early as possible.

Recommended Schedules – by age at which child presents for MeNZB™

NB shaded areas indicate routine schedule vaccines already given. If child is late, give routine vaccines as soon as the child presents (see Immunisation Handbook page 272).

1. 6 week old children: Routine schedule concurrent with MeNZB™

6 wks	MeNZB™	DTaP-IPV	Hib-Hep	
3 mths	MeNZB™	DTaP-IPV	Hib-Hep	
5 mths	MeNZB™	DTaP-IPV		HepB

2. Children aged >6 weeks to <2 months: 1st dose of routine schedule at 6 weeks, 1st dose MeNZB™ at 6 weeks – 2 months

6 wks		DTaP-IPV	Hib-Hep	
6 wks – 2 mths	MeNZB™			
3 mths [#]	MeNZB™	DTaP-IPV	Hib-Hep	
5 mths [*]	MeNZB™	DTaP-IPV		HepB

[#] NB at least 4 weeks after MeNZB™ dose 1. ^{*} NB 6 weeks after MeNZB™ dose 2.

3. Children aged ≥2 months to <3 months: 1st dose routine schedule at 6 weeks, 1st dose MeNZB™ at 2–3 months

6 wks		DTaP-IPV	Hib-Hep	
2–3 mths	MeNZB™			
3 mths		DTaP-IPV	Hib-Hep	
3–4 mths [#]	MeNZB™			
5 mths [*]	MeNZB™	DTaP-IPV		HepB

[#] NB at least 4 weeks after MeNZB™ dose 1. ^{*} NB 6 weeks after MeNZB™ dose 2.

4. Children aged 3 months: 1st dose routine schedule at 6 weeks, 1st dose MeNZB™ at 3 months

6 wks		DTaP-IPV	Hib-Hep	
3 mths	MeNZB™	DTaP-IPV	Hib-Hep	
5 mths [#]	MeNZB™	DTaP-IPV		HepB
6.5 mths [*]	MeNZB™			

[#] NB at least 4 weeks after MeNZB™ dose 1. ^{*} NB 6 weeks after MeNZB™ dose 2.

5. Children aged ≥3 months to 4 months: 1st dose routine schedule at 6 weeks 1st dose MeNZB™ at 3–4 months

6 wks		DTaP-IPV	Hib-Hep	
3 mths		DTaP-IPV	Hib-Hep	
3–4 mths	MeNZB™			
5 mths [#]	MeNZB™	DTaP-IPV		HepB
6.5 mths [*]	MeNZB™			

[#] NB at least 4 weeks after MeNZB™ dose 1. ^{*} NB 6 weeks after MeNZB™ dose 2.

6. Children aged ≥4 months to 5 months: 1st dose routine schedule at 6 weeks, 1st dose MeNZB™ at 4–5 months

6 wks		DTaP-IPV	Hib-Hep	
3 mths		DTaP-IPV	Hib-Hep	
4–5 mths	MeNZB™			
5 mths		DTaP-IPV		HepB
6.5 mths [#]	MeNZB™			
8 mths [*]	MeNZB™			

[#] NB at least 4 weeks after MeNZB™ dose 1. ^{*} NB 6 weeks after MeNZB™ dose 2.

7. Children aged 5 months: 1st dose routine schedule at 6 week, 1st dose MeNZB™ at 5 months

6 wks		DTaP-IPV	Hib-Hep	
3 mths		DTaP-IPV	Hib-Hep	
5 mths	MeNZB™	DTaP-IPV		HepB
6.5 mths [#]	MeNZB™			
8 mths [*]	MeNZB™			

[#] NB at least 4 weeks after MeNZB™ dose 1. ^{*} NB 6 weeks after MeNZB™ dose 2.

8. Children aged >5 months, who have completed the routine schedule should receive 3 doses of MeNZB™ at 6 week intervals.