

# MeNZB<sup>®</sup>

Single dose vial,  
Suspension for Injection,  
Meningococcal group B Outer Membrane Vesicle (OMV) vaccine

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about MeNZB. It does not contain all the available information. It does not take the place of talking to your doctor or nurse.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you/your child being given MeNZB against the benefits they expect it will have for you.

If you have any concerns about this vaccine, ask your doctor or nurse.

Keep this leaflet. You may need to read it again.

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### What MeNZB is used for

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MeNZB is a vaccine used to help prevent meningococcal disease (meningitis, blood poisoning). Meningitis and blood poisoning occur when bacteria (most commonly *Neisseria meningitidis* - meningococci) infect the tissue lining the brain and/or the bloodstream. Meningococcal disease can be a highly infectious and sometimes fatal.

**Please note that MeNZB can only protect you from meningococcal disease caused by the New Zealand strain of meningococci (serogroup B *Neisseria meningitidis* (P1.7b.4)), which is very common in New Zealand. It will not protect you from**

**meningitis caused by other groups or types of meningococci or other bacteria.**

### How it works

MeNZB works by causing your body to produce its own protection (or antibodies), against the meningococcal bacteria. It is believed that if a vaccinated person comes into contact with *Neisseria meningitidis*, the body is usually ready to destroy it. Most people will produce enough antibodies to protect against meningococcal disease. However, as with all vaccines, 100% protection cannot be guaranteed.

Following a course of three injections your body usually takes four weeks after vaccination to develop protection against *Neisseria meningitidis*.

MeNZB can be used in adults and children and infants over six weeks of age. Vaccination is recommended for all under 20 years of age.

The chance of a severe reaction from MeNZB vaccine is very small, but the risks from not being vaccinated against meningococcal disease may be very serious.

Please talk to your doctor or nurse if you have any questions.

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### Before you are given MeNZB

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#### Do Not Have MeNZB If:

- You/your child have had a severe allergic reaction to MeNZB, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- If you/your child have had MeNZB before and became unwell, tell your doctor or nurse before the next dose is given.
- You/your child have a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.
- The expiry date printed on the pack has passed
- The packaging is torn or shows signs of tampering.
- If you are not sure whether you/your child should have MeNZB, talk to your doctor or nurse.

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### Before you receive MeNZB:

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#### Tell your doctor or nurse if :

- You have /your child has any medical conditions, such as:
  - a bleeding disorder.Sometimes MeNZB may need to be given differently

in people with bleeding problems

- an immune deficiency condition (eg. are HIV positive)
- brain disease or Central Nervous System (CNS) disease such as epilepsy or a tendency to febrile convulsions (seizures /fits due to a high fever).
- You have/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- You have/your child has a severe infection with a high temperature. Your doctor may decide to delay vaccination until the illness has passed. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.

***Tell your doctor or nurse if you have/your child has reacted to previous vaccination, including:***

- life-threatening allergic reaction
- difficulty breathing
- swelling of the throat
- fainting or collapse
- shock-like state or being unresponsive for a long period of time
- fits or convulsions
- high temperature (greater than 40°C)
- crying or screaming lasting for more than 3 hours
- severe skin reaction at the injection site.

Some vaccines may be affected by other vaccines or medicines. Your doctor or nurse will be able to tell you what to do if MeNZB is to be given with another vaccine or medicine.

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## **How MeNZB is given**

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The doctor or nurse will give MeNZB as an injection. If you have any concerns about how this vaccine is to be given, talk to your doctor or nurse.

### ***How much is given***

The dose of MeNZB is 0.5 ml

### ***How it is given***

The vaccine (0.5 ml) is given by injection into a muscle (intramuscular injection), preferably in the anterolateral thigh in infants/toddlers and in the deltoid region (near the shoulder) of the non dominant arm in toddlers, older children, adolescents and adults.

The vaccine must not be injected into a vein, (intravenously), superficially (subcutaneously), or into the skin itself (intradermally).

### ***When it will be given***

For infants less than 6 months of age, four doses are recommended. The doses should be administered at 6 weeks, 3 months, 5 months and 10 months of age (with an interval of 6 weeks between the 1st and 2nd dose, of 8 weeks between the 2nd and the 3rd dose and of not less than 5 months between the 3rd and the 4th dose).

For infants over the age of 6 months, children and adolescents, three doses, each of 0.5 ml, are recommended with an interval of 6 weeks between doses.

It is important to return at the recommended times for follow up doses.

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## **After having MeNZB**

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### ***Things you must do:***

Keep a record of you/your child's vaccinations, and update this after each injection/dose.

Keep your follow-up appointments with your doctor, nurse or clinic.

It is important to have all three (four for infants) doses of MeNZB vaccine at the appropriate times to make sure the vaccine has the best chance of providing protection against meningococcal disease.

### ***Things to be careful of:***

Be careful driving or operating machinery until you know how MeNZB vaccine affects you.

Dizziness has been very rarely reported following vaccination. This may temporarily affect the ability to drive or use machines.

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## **Side effects**

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Tell your doctor or nurse as soon as possible if you do not/your child does not feel well after receiving a dose of MeNZB.

MeNZB may help to protect you /your child from meningococcal disease but it may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment. However, the chance of your child having a serious side effect is less than the chance of your child having a permanent injury from the infections.

Ask your doctor or nurse to answer any questions you may have.

Most unwanted effects with MeNZB are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site (local reactions).

### **Mild effects**

**Tell your doctor or nurse if you notice any of the following that are troublesome or ongoing:**

- local reaction around the injection site such as tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps ,
- redness, bruising , itchiness or swollen lymph glands at the injection site
- swelling around the armpit
- flushing or redness of the skin
- headaches
- dizziness
- tiredness, weakness or fatigue
- generally feeling unwell, fever (between 38°C and 40°C)
- loss of appetite, or feeling sick (nausea), vomiting or diarrhoea
- restlessness, unusual crying (for more than an hour).

### **More serious effects (rare)**

**As with all vaccines given by injection there is a very small risk of serious allergic reaction. If any of the following happen, tell your doctor, or nurse immediately or go to the Accident and Emergency Department at your nearest hospital:**

- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties

- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
- unusual tiredness or weakness that is sudden and severe, muscular aches and pains
- convulsions/fits, collapse or periods of unconsciousness
- fever over 40°C
- crying for 3 hours or more .

These are very serious side effects that usually occur within the first few hours of vaccination. You/your child may need urgent medical attention or admission to hospital

All of these side effects are very rare.

**Tell your doctor or nurse if you notice any of the following:**

- fever (greater than 38°C) and/or chills
- neurological reactions (reactions involving the nervous system).

These reactions are rare but can be serious.

Other side effects not listed above may occur in some patients. Tell your doctor or nurse if you notice anything that is making you/your child feel unwell.

Do not be alarmed by this list of possible side effects.

You/your child may not experience any of them.

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## **Product description**

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### **What it looks like**

MeNZB is supplied as a single dose (0.5 ml) in a glass container. It is an off-white, opalescent (pearly) liquid.

## **Ingredients**

1 dose (0.5 ml) contains:

### **Active ingredient:**

Outer membrane vesicles from *Neisseria meningitidis* group B (strain NZ 98/254) measured as amount of total protein\*

.....  
....25 microgram

\* Adsorbed on aluminium hydroxide (1.65 milligram)

### **Excipients:**

- Sodium chloride
- Histidine buffer

### **Sponsor**

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### **Date of preparation:**

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