

MENACTRA®

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you are vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Menactra vaccine is and what it is used for
- Before you are given Menactra vaccine
- How Menactra vaccine is given
- Possible side effects
- Storing Menactra vaccine
- Further information

What Menactra vaccine is and what it is used for

Menactra is a vaccine.

Vaccines are used to protect you against infectious diseases.

Menactra vaccine is given to protect persons 2 through 55 years of age against meningococcal disease caused by four groups of *Neisseria meningitidis* (A, C, Y and W-135). The use of this vaccine should be in accordance with official recommendations. It allows the body to produce enough antibodies to provide a defence against the bacteria that cause meningococcal disease. However, as with all vaccines, 100% protection cannot be guaranteed.

Menactra vaccine will not prevent meningitis (an infection of the brain and spinal cord coverings) caused by other groups of *Neisseria meningitidis* or meningitis caused by different kinds of microbes.

Before you are given Menactra vaccine

When you must not be given it

- Do not have Menactra vaccine if you are allergic (hypersensitive) to the active substance or any of the other ingredients of Menactra vaccine listed in the FURTHER INFORMATION section
- If you have an illness with febrile or acute infection, the vaccination shall be postponed until after you have recovered
- If you have been previously diagnosed with Guillain-Barre syndrome
- Children younger than 2 years of age or adults older than 55 years of age

Take special care with Menactra vaccine

- Tell your doctor if you have been previously diagnosed with Guillain-Barre syndrome or any brain disorder
- Tell your doctor if you are pregnant or nursing

If you become aware that you were pregnant when you received Menactra vaccine, please discuss this with your doctor or contact sanofi pasteur at 1800 829 468 (in Australia) or 0800727 838 (in New Zealand) for more information.

- Tell your doctor if you have an immune deficiency condition

Your doctor should make sure the benefits of vaccination outweigh the risks when recommending Menactra vaccine.

Taking other medicines

- Medicines that may reduce your immune response: such as corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. Tell your doctor if you have been treated with such medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Having other vaccines

- Your doctor will advise you if Menactra vaccine is to be given with another vaccine. Menactra vaccine may be given at the same time as typhoid vaccines and Td (tetanus and diphtheria) vaccines using separate syringes and into separate limbs.

How Menactra vaccine is given

Menactra vaccine is administered to you by your doctor or your nurse.

A single dose of Menactra vaccine (0.5 mL) is injected into the muscle of the upper arm (preferably) of persons 2 through 55 years of age.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible side effects

Like all medicines, Menactra vaccine can cause side effects, although not everybody gets them.

The most common local side effects with Menactra vaccine include:

- pain, tenderness, redness, hardness and swelling at the injection site

Systemic side effect include:

- headache, tiredness (fatigue), feeling unwell (malaise)
- joint pain (arthralgia)
- fever, chills
- loss of appetite, diarrhoea, vomiting
- rash
- irritability, drowsiness (in children)

These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.

Other side effects that have been reported very rarely include:

- hypersensitivity reactions such as wheezing, difficulty breathing, upper airway swelling, low blood pressure (hypotension), skin reactions for which symptoms may include itchiness of the skin (urticaria, pruritus) and redness of the skin (erythema)
- sudden severe allergic reaction, for which symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylactic/anaphylactoid reaction)
- neurological disorders that may result in confusion, numbness or tingling, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (Guillain-Barre syndrome, acute disseminated encephalomyelitis, transverse myelitis)
- dizziness
- fainting
- convulsion
- drooping eyelid and sagging muscles on one side of the face (facial palsy)
- tingling or numbness of the hands or feet (paraesthesia)
- sore, aching muscles (myalgia)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

After using Menactra Vaccine

Storage

Menactra vaccine is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Menactra vaccine

- Keep out of reach and sight of children.
- Keep Menactra vaccine in the original pack until it is time for it to be given.
- **Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze Menactra vaccine.**

Do not use Menactra vaccine after the expiry date which is stated on the carton after EXP.

Do not have Menactra vaccine if the packaging is torn or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What Menactra vaccine contains

The active substance is 4 µg of each polysaccharide per serogroup A, C, Y and W-135 conjugated to approximately 48 µg diphtheria toxoid.

The other ingredients are excipients: sodium chloride, sodium phosphate - dibasic anhydrous and sodium phosphate - monobasic.

No adjuvant or preservative is added.

What Menactra vaccine looks like and contents of the pack

Each pack of Menactra vaccine contains

1 vial containing a single dose (0.5 mL) of a clear to slightly turbid liquid

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Australian Sponsor*

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