

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

What Menactra is and what it is used for

Menactra is a vaccine.

Vaccines are used to protect you against infectious diseases.

Menactra is given to protect persons 9 months 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 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

When you must not be given it

- Do not have Menactra if you are allergic (hypersensitive) to the active substance or any of the other ingredients of Menactra listed in the FURTHER INFORMATION section
- Children younger than 9 months of age or adults older than 55 years of age

Take special care with Menactra

- If you have an illness with febrile or acute infection, the vaccination shall be postponed until after you have recovered
- **Tell your doctor if you have been previously diagnosed with Guillain-Barre syndrome**
- **Tell your doctor if you are pregnant or nursing**
If you become aware that you were pregnant when you received Menactra, please discuss this with your doctor or contact sanofi pasteur at 1800

818 806 (in Australia) or 0800 283 684 (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.

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 is to be given at the same time as another vaccine.

How Menactra vaccine is given

Method of administration

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

Menactra is injected into the muscle of the thigh or upper arm (preferably) depending on your age and muscle mass.

Dose and Schedule

A single dose of Menactra is 0.5 mL.

- In children 9 through 23 months of age, Menactra is given as 2 doses 3 months apart.
- Individuals 2 through 55 years of age receive a single dose.

For some individuals a booster dose may be recommended by your doctor.

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

Possible side effects

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

The most common local side effects with Menactra include:

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

Systemic side effects include:

- headache, tiredness (fatigue), feeling unwell (malaise)
- joint pain (arthralgia)
- fever, chills
- loss of appetite, diarrhoea, vomiting
- rash
- irritability, drowsiness, abnormal crying (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)
- extensive limb swelling
- swollen glands in the neck, armpit or groin

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

Storage

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

- Keep out of reach and sight of children.
- Keep Menactra 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.**

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

Do not have Menactra 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 contains

Active ingredients:

- 4 mcg of each meningococcal polysaccharide Group A, C, Y and W-135 conjugated to approximately 48 mcg diphtheria toxoid

Other ingredients:

- Sodium chloride
- Dibasic sodium phosphate
- Monobasic sodium phosphate

Menactra vials are not made with natural rubber latex.

No adjuvant or preservative is added.

What Menactra looks like and contents of the pack

Each pack of Menactra contains:

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

Name and Address of Australian Sponsor

sanofi-aventis australia pty ltd

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