

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

MenQuadfi™

Meningococcal (Groups A, C, Y, W) Polysaccharide Tetanus Toxoid Conjugate Vaccine

Read this carefully before you or your child receive **MenQuadfi**. This leaflet is a summary and will not tell you everything about this product. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MenQuadfi**.

What is MenQuadfi used for?

MenQuadfi is a vaccine. It is used to help protect you or your children against infections caused by bacteria (germs) called "*Neisseria meningitides*" types A, C, W and Y. *Neisseria meningitidis* can be passed from person to person and can cause meningitis, an inflammation of the tissues that surround the brain and spinal cord, or septicemia, an infection of the blood. Both can result in serious disease with lasting effects and possibly death. MenQuadfi will not protect against disease caused by any other infectious agents.

How does MenQuadfi work?

MenQuadfi causes your body to produce its own natural protection against bacteria that can cause meningococcal diseases ("*Neisseria meningitides*" types A, C, W and Y). After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help your body to fight disease. If a vaccinated person comes into contact with one of the germs that cause this disease, the body is usually ready to destroy it. The amount of time it takes for your body to develop enough antibodies to protect you from meningococcal diseases can vary. It can take a few weeks after your vaccination.

The great majority of people who get vaccinated with MenQuadfi will produce enough antibodies to protect them against meningococcal diseases (groups A, C, W and Y). However, as with all vaccines, 100% protection cannot be guaranteed.

What are the ingredients in MenQuadfi?

Medicinal ingredients: Meningococcal (groups A, C, W and Y) polysaccharides conjugated to tetanus toxoid protein carrier.

Non-medicinal ingredients: Sodium Chloride, 50 mM Sodium Acetate (pH 6.0), Sterile Water for Injection.

MenQuadfi comes in the following dosage forms:

MenQuadfi is a clear, colourless liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

Do not receive MenQuadfi if you or your child:

- are allergic to active substances or any of the other ingredients in MenQuadfi. Symptoms may include rash, itching, difficulty breathing, shortness of breath or swelling of the face,

lips, throat, or tongue. If you are not sure if you are allergic, talk to your doctor, pharmacist or nurse before you receive MenQuadfi.

- are a person with a known history of Guillain-Barré Syndrome unless the potential benefits outweigh the risks of administration.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child receive MenQuadfi. Talk about any health conditions or problems you or your child may have, including if you or your child:

- ever fainted from an injection. Fainting, sometimes with falling, can occur (mostly in adolescents and young adults) following, or even before, any injection with a needle.
- a disease weakening your body's natural defenses (immune system). Your response to vaccines may not be optimal.
- thrombocytopenia or bleeding disorders or receiving anticoagulant therapy.
- illness with high fever (over 38°C). There is no need to delay vaccination for a minor infection such as a cold. However, talk to your doctor, pharmacist or nurse first.
- pregnancy and/or breast-feeding

Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

MenQuadfi may not have an optimal effect if used with medicines that weaken the immune system such as high-dose corticosteroids or chemotherapy.

How to take MenQuadfi:

MenQuadfi is given by a doctor, pharmacist, or nurse as a 0.5 ml injection in the muscle in the upper arm or in the thigh depending on your age and muscle mass.

Usual dose:

A single dose is 0.5 mL.

Overdose:

If you think you, or a person you are caring for, have received too much MenQuadfi, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable to this vaccine.

What are possible side effects from using MenQuadfi?

Like all medicines, this vaccine can cause side effects, although not everybody gets them. These are not all the possible side effects you or your child may feel when taking MenQuadfi. If you experience any side effects not listed here, contact your healthcare professional.

The following side effects can be seen after the use of MenQuadfi in children 12-23 months of age.

Very common (may affect more than 1 in 10 people)

- Tenderness, redness, or swelling where the injection was given
- Feeling irritable
- Crying
- Loss of appetite
- Feeling drowsy

Common (may affect up to 1 in 10 people)

- Fever
- Vomiting
- Diarrhea

The following side effects may happen in children (2years of age and older), adolescents, adults and the elderly.

Very common (may affect more than 1 in 10 people)

- Pain where the injection was given
- Muscle pain
- Headache
- Generally feeling unwell

Common (may affect up to 1 in 10 people)

- Redness or swelling where the injection was given
- Fever

Uncommon (may affect up to 1 in 100 people)

- Itching, warmth, bruising or rash where the injection was given
- Vomiting
- Feeling dizzy
- Nausea
- Fatigue

The following side-effects can happen in any age-group.

Not Known (cannot be estimated from available data)

- Hypersensitivity including anaphylaxis
- Fits (convulsions) with or without fever

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you or your child experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store in a refrigerator (+2°C to +8°C).

Do not freeze.

Keep out of reach and sight of children.

If you want more information about MenQuadfi:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website www.sanofi.com/en/canada, or by calling 1-888-621-1146 (no charge).

This leaflet was prepared by Sanofi Pasteur Limited.

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