

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MenQuadfi (solution for injection)

Meningococcal (groups A, C, Y, W) polysaccharide tetanus toxoid conjugate vaccine.

Sugar free.

Read all of this leaflet carefully before you or your child is vaccinated, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do not share MenQuadfi with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- If you or your child gets any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What MenQuadfi is and what it is used for
2. What you need to know before you or your child are given MenQuadfi
3. How MenQuadfi is given
4. Possible side effects
5. How to store MenQuadfi
6. Contents of the pack and other information

1. What MenQuadfi is and what it is used for

What MenQuadfi is used for

MenQuadfi is a vaccine that can be given to children from 1 year of age, adolescents and adults.

MenQuadfi helps to protect against infections caused by types of bacteria (germs) called "*Neisseria meningitidis*", specifically against types A, C, W and Y.

Neisseria meningitidis bacteria (also called meningococci) can cause life-threatening infections, such as:

- Meningitis – an inflammation of the tissues that surround the brain and spinal cord;
- Septicaemia – an infection of the blood.

Both infections can result in serious disease with long lasting effects or possibly death.

MenQuadfi should be used in accordance with official national guidelines.

How the vaccine works

MenQuadfi works by stimulating the vaccinated person's natural defense (immune system), to produce protective antibodies against the bacteria.

MenQuadfi only helps to protect against illnesses caused by *Neisseria meningitidis* types A, C, W and Y.

- It does not protect against infections caused by other types of *Neisseria meningitidis*.
- It does not protect against meningitis or septicaemia caused by other bacteria or viruses.

As with any vaccine, MenQuadfi may not fully protect all the people who are vaccinated.

2. What you need to know before you or your child are given MenQuadfi

Do not receive MenQuadfi if you or your child

- Is allergic to any of the active substances or any of the other ingredients of this vaccine (listed

in section 6) or have experienced a previous allergic reaction to this vaccine.

If you are not sure, talk to your doctor, pharmacist or nurse before you or your child is given MenQuadfi.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before vaccination with MenQuadfi if you or your child has:

- An infection with high temperature (over 38 °C). If this applies, the vaccination will be given after the infection is under control. There is no need to delay vaccination for a minor infection such as a cold. However, talk to your doctor, pharmacist or nurse first.
- A bleeding problem or bruise easily.
- Ever fainted from an injection. Fainting, sometimes accompanied by falling, can occur (mostly in adolescents) after, or even before, any injection.
- A weak immune system (such as due to HIV infection, other disease, or use of a medicine that affect the immune system), as you or your child may not fully benefit from having MenQuadfi.

If any of the above apply to you or your child (or you are not sure whether they apply), talk to your doctor, pharmacist or nurse before you or your child is given MenQuadfi.

As with any vaccine, MenQuadfi may not fully protect all of those who get the vaccine.

Other medicines and MenQuadfi

Tell your doctor, pharmacist, or nurse if you or your child is taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

This includes all complementary or traditional medicines.

In particular, tell your doctor, pharmacist, or nurse if you or your child is taking any medicines that affect your immune system, such as:

- high-dose corticosteroids

- chemotherapy.

MenQuadfi may be given at the same time as other vaccines at separate injection sites during the same visit. These include the vaccines that protect against measles, mumps, rubella, varicella, diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b, hepatitis B, pneumococcal and human papillomavirus infections

Pregnancy and breastfeeding

If you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before receiving MenQuadfi.

Driving and using machines

MenQuadfi is not likely to affect your ability to drive, cycle or use machines. However, do not drive, cycle or use any machines if you are not feeling well.

MenQuadfi contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, this means that it is essentially sodium free.

3. How MenQuadfi is given

MenQuadfi is given by a doctor or nurse as a 0,5 mL injection in the muscle. It is given in the upper arm or in the thigh depending on the age and how much muscle you or your child has.

4. Possible side effects

Like all vaccines, MenQuadfi can cause side effects, although not everybody gets them.

If you or your child get any of these symptoms after the vaccination. Contact your doctor

immediately. This could be signs of an allergic reaction:

- itchy skin rash
- shortness of breath
- swelling of the face or tongue.

Possible side effects in children aged 12 to 23 months:

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

- 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 children)

- fever
- vomiting
- diarrhoea.

Uncommon (may affect up to 1 in 100 children)

- difficulty sleeping
- hives
- itching, bruising, firmness or rash where the injection was given.

Not known (frequency cannot be estimated from the available data)

- Fits (convulsions) with or without fever.

Possible side effects in children (2 years of age and older), adolescents and adults:

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 (feeling tired).

Rare (may affect up to 1 in 1 000 people)

- enlarged lymph nodes
- diarrhoea, stomach pain
- hives, itching, rash
- pain in the arms or legs
- chills, pain in the armpit
- injection site firmness.

Not known (frequency cannot be estimated from the available data)

- Fits (convulsions) with or without fever.

Reporting of side effects

If you or your child gets any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store MenQuadfi

KEEP THIS VACCINE OUT OF REACH OF CHILDREN.

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

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

Do not freeze.

Do not throw away any medicines via wastewater or household waste. Return all unused medicine to your pharmacist. These measures will help to protect the environment.

6. Contents of the pack and other information

What MenQuadfi contains

One dose (0,5 mL) contains:

- The active substances are

Neisseria meningitidis group A polysaccharide¹ 10 micrograms

Neisseria meningitidis group C polysaccharide¹ 10 micrograms

Neisseria meningitidis group Y polysaccharide¹ 10 micrograms

Neisseria meningitidis group W polysaccharide¹ 10 micrograms

¹Conjugated to tetanus toxoid carrier protein 55 micrograms

- The other ingredients are
 - sodium chloride
 - sodium acetate
 - water for injections.

What MenQuadfi looks like and contents of the pack

MenQuadfi is a clear, colourless solution for injection.

MenQuadfi is available in packs of 1 or 5 single dose (0,5 mL) vials. Not all pack sizes may be marketed.

Holder of certificate of registration

sanofi-aventis south africa (pty) ltd

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