

## **Package leaflet: Information for the user**

### **MenQuadfi solution for injection**

Meningococcal group A, C, W and Y conjugate vaccine

**Read all of this leaflet carefully before you or your child are given this vaccine because it contains important information for you or your child.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others
- If you or your child get 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**

MenQuadfi (MenACWY) 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 a type of bacteria (germs) called “*Neisseria meningitidis*”, specifically against types A, C, W and Y.

*Neisseria meningitidis* bacteria (also called meningococci) can be passed from person to person and can cause serious and sometimes 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 natural defence (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.

#### **2. What you need to know before you are given MenQuadfi**

**Do not have MenQuadfi if you or your child**

- are 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 are given MenQuadfi.

**Warnings and precautions**

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

- 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 are given MenQuadfi.

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

**Other medicines and MenQuadfi**

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

In particular, tell your doctor, pharmacist, or nurse if you or your child are 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 a separate injection site during the same visit. These include measles, mumps, rubella, varicella, diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b, hepatitis B, pneumococcal, human papillomavirus and *Neisseria meningitidis* type B vaccines.

**Pregnancy and breast-feeding**

If you are pregnant, breast-feeding, 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, that is to say 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 have.

#### **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:

- itchy skin rash
- difficulty breathing, shortness of breath
- swelling of the face, lips, throat, or tongue

Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away. This could be signs of an allergic reaction.

#### **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

**Very rare** (may affect less than 1 in 10 000 people)

- sudden, severe allergic reactions with difficulty breathing, hives, swelling of the face and throat, a fast heartbeat, dizziness, weakness, sweating and loss of consciousness

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

- allergic reaction
- fits (convulsions) with or without fever

### **Side effects in children aged 12 to 23 months**

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

- tenderness/pain, 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
- diarrhoea

**Uncommon** (may affect up to 1 in 100 people)

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

**Very rare** (may affect less than 1 in 10 000 people)

- sudden, severe allergic reactions with difficulty breathing, hives, swelling of the face and throat, a fast heartbeat, dizziness, weakness, sweating and loss of consciousness

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

- allergic reaction
- fits (convulsions) with or without fever

### **Reporting of side effects**

If you or your child get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). 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 the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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

Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What MenQuadfi contains**

#### **One dose (0.5 mL) contains:**

- The active substances are:

- <i>Neisseria meningitidis</i> group A polysaccharide <sup>1</sup>	10 micrograms
- <i>Neisseria meningitidis</i> group C polysaccharide <sup>1</sup>	10 micrograms
- <i>Neisseria meningitidis</i> group Y polysaccharide <sup>1</sup>	10 micrograms
- <i>Neisseria meningitidis</i> group W polysaccharide <sup>1</sup>	10 micrograms
- <sup>1</sup> Conjugated to tetanus toxoid carrier protein	55 micrograms
- The other ingredients are
  - sodium chloride
  - sodium acetate (E 262)
  - 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, 5 or 10 single dose (0.5 mL) vials and pack of 1 single dose vial (0.5 mL) co-packaged with 1 single use empty syringe and 2 needles.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Sanofi Winthrop Industrie  
82 Avenue Raspail  
94250 Gentilly  
France

### **Manufacturer**

Sanofi Winthrop Industrie  
Voie de l'Institut  
Parc Industriel d'Incarville  
BP 101  
27100 Val de Reuil  
France

Sanofi-Aventis Zrt.  
Building DC5  
Campona utca 1.  
Budapest, 1225  
Hungary