

1 **PATIENT INFORMATION LEAFLET**

2

3 **SCHEDULING STATUS** S4

4

5 **MenQuadfi (solution for injection)**

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

7

8 **Read all of this leaflet carefully before you or your child is vaccinated, because it contains**

9 **important information for you.**

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

15

16 **What is in this leaflet**

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

23

24 **1. What MenQuadfi is and what it is used for**

25 **What MenQuadfi is used for**

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

27 MenQuadfi helps to protect against infections caused by a type of types bacteria (germs) called

28 “*Neisseria meningitidis*”, specifically against A, C, W and Y.

29

30 *Neisseria meningitidis* bacteria (also called meningococci) can be

31 threatening infections, such as:

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

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

35 MenQuadfi should be used in accordance with official national guidelines.

36

37 **How the vaccine works**

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

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

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

44

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

46

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

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

- 49 • are allergic to any of the active substances or any of the other ingredients of this vaccine
50 (listed in section 6) or have experienced a previous allergic reaction to this vaccine.

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

53

54 **Warnings and precautions**

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

56 have:

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

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

68

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

70

71 **Other medicines and MenQuadfi**

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

74 This includes all complementary or traditional medicines.

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

- 77 • high-dose corticosteroids
- 78 • chemotherapy.

79

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

84

85 **Pregnancy and breastfeeding**

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

88

89 **Driving and using machines**

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

92

93 **MenQuadfi contains sodium**

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

96

97 **3. How MenQuadfi is given**

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

100

101 **4. Possible side effects**

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

103 If you or your child get any of these symptoms after the vaccination;

- 104 • itchy skin rash
- 105 • shortness of breath
- 106 • swelling of the face or tongue.

107 Contact your doctor immediately. This could be signs of an allergic reaction.

108

109 **Possible side effects in children aged 12 to 23 months:**

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

- 111 • tenderness, redness, or swelling where the injection was given

112 • feeling irritable

113 • crying

114 • loss of appetite

115 • feeling drowsy

116

117 **Common** (may affect up to 1 in 10 children)

118 • fever

119 • vomiting

120 • diarrhoea

121

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

123 • difficulty sleeping

124 • hives

125 • itching, bruising, firmness, or rash where the injection was given

126

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

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

129 • pain where the injection was given

130 • muscle pain

131 • headache

132 • generally feeling unwell

133

134 **Common** (may affect up to 1 in 10 people)

135 • redness or swelling where the injection was given

136 • fever

137

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

139 • itching, warmth, bruising or rash where the injection was given

- 140 • vomiting
- 141 • feeling dizzy
- 142 • nausea
- 143 • fatigue (feeling tired)

144

145 **Rare** (may affect up to 1 in 1,000 people)

- 146 • enlarged lymph nodes
- 147 • diarrhoea, stomach pain
- 148 • hives, itching, rash
- 149 • pain in the arms or legs
- 150 • chills, pain in the armpit
- 151 • injection site firmness

152

153 **Reporting of side effects**

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

156 You can report any side effects directly to Sanofi's Pharmacovigilance Unit at

157 za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

158 You can also report side effects via the **6.04 Adverse Drug Reaction Reporting Form**, found
159 online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

160 By reporting side effects, you can help provide more information on the safety of this medicine.

161

162 **5. How to store MenQuadfi**

163 **KEEP THIS VACCINE OUT OF THE SIGHT AND REACH OF CHILDREN.**

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

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

166 Do not freeze.

167 Do not throw away any medicines via wastewater or household waste. Return all unused medicine

168 to your pharmacist. These measures will help to protect the environment.

169

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

171 **What MenQuadfi contains**

172 **One dose (0,5 mL) contains:**

173 - The active substances are

174 *Neisseria meningitidis* group A polysaccharide¹ 10 micrograms

175 *Neisseria meningitidis* group C polysaccharide¹ 10 micrograms

176 *Neisseria meningitidis* group Y polysaccharide¹ 10 micrograms

177 *Neisseria meningitidis* group W polysaccharide¹ 10 micrograms

178 - ¹Conjugated to tetanus toxoid carrier protein 55 micrograms

179 - The other ingredients are

180 - sodium chloride

181 - sodium acetate

182 - water for injections

183

184 **What MenQuadfi looks like and contents of the pack**

185 MenQuadfi is a clear colourless solution for injection.

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

188

189 **Holder of Certificate of Registration:**

190 sanofi-aventis south africa (pty) ltd

191 Hertford Office Park, Building I, 5th Floor

192 90 Bekker Road, Vorna Valley

193 Midrand 2196

194 Tel: 011 256 3700

195

196 **Date of registration:**

197 19 September 2023