MENQUADFI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor, nurse or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details

1. Why am I using MenQuadfi?

MenQuadfi is a vaccine. It is used to help protect you or your child against infections caused by a bacteria (germs) called "*Neisseria meningitides*" types A, C, W-135 and Y. MenQuadfi can be given to children (12 months of age and above), adolescents, adults and the elderly.

For more information, see Section 1. Why am I using MenQuadfi? in the full CMI.

2. What should I know before I use MenQuadfi?

Do not use if you have ever had an allergic reaction to MenQuadfi or any of the ingredients listed at the end of the CMI.

Talk to your doctor, nurse or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MenQuadfi? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MenQuadfi and may affect how it works. Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use MenQuadfi?

MenQuadfi is given by your doctor, nurse or pharmacist.

More instructions can be found in Section 4. How do I use MenQuadfi? in the full CMI.

5. What should I know-after using MenQuadfi?

Things you should do	 Call your doctor, nurse or pharmacist straight away if you: notice signs of allergic reaction which include rash, itching, difficulty breathing, shortness of breath or swelling of the face, lips, throat or tongue. Driving or using machines MenQuadfi is not likely to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell.
Looking after your medicine	MenQuadfi is usually stored in the doctor's surgery or clinic, or at a pharmacy. However, if you need to store MenQuadfi: keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section 5. What should I know after using MenQuadfi? in the full CMI.

6. Are there any side effects?

Serious side effects can include allergic reactions. **See your doctor immediately if you notice this.** Common side effects in children (2 years of age and older), adolescents, adults and elderly include pain, redness, or swelling at the injection site, muscle pain, headache, generally feeling unwell and fever. In children 12-23 months of age, common side effects include tenderness, redness or swelling at the injection site, feeling irritable, crying, loss of appetite, feeling drowsy, fever, vomiting and diarrhoea.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

MenQuadfi

Active ingredient(s): Meningococcal Polysaccharides Groups A, C, Y and W-135

Consumer Medicine Information (CMI)

This leaflet provides important information about using MenQuadfi. You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using MenQuadfi.

This vaccine can be given to adults and children so you may be reading this leaflet for you or for your child.

Where to find information in this leaflet:

- 1. Why am I using MenQuadfi
- 2. What should I know before I use MenQuadfi?
- 3. What if I am taking other medicines?
- 4. How do I use MenQuadfi?
- 5. What should I know while using MenQuadfi?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using MenQuadfi

MenQuadfi contains the active ingredients meningococcal polysaccharide groups A, C, W-135 and Y.

MenQuadfi is a vaccine. It is used to help protect you or your child against infections caused by a bacteria (germs) called "*Neisseria meningitides*" types A, C, W and Y.

Neisseria meningitidis is passed from person to person and can cause meningitis, an inflammation of the tissues that surround the brain and spinal cord, or septicaemia, an infection of the blood. Both can result in serious disease with lasting effects and possibly death.

MenQuadfi can be given to children (12 months of age and above), adolescents, adults and the elderly.

MenQuadfi stimulates the body's natural defenses (immune system), to produce its own protection (antibodies) against the bacteria ("*Neisseria meningitidis*" types A, C, W-135 and Y) that may cause the meningococcal disease. However, as with all vaccines, 100% protection cannot be guaranteed.

MenQuadfi will not prevent meningitis (an infection of the brain and spinal cord coverings) caused by other groups of *Neisseria meningitidis*.

2. What should I know before I use MenQuadfi?

Warnings

Do not use MenQuadfi:

 if you are allergic to the active ingredients or any of the ingredients listed at the end of this leaflet.
 Symptoms of allergic reaction 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, nurse or pharmacist before you receive MenQuadfi.

Always check the ingredients to make sure you can receive this vaccine.

Tell your doctor, nurse or pharmacist if you 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 disease weakening your body's natural defences (immune system). Your response to vaccines may not be optimal.
- ever fainted from an injection., Fainting sometimes with falling, can occur (mostly in adolescents and young children) during, following, or even before, any injection with a needle.

After vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, plan to become pregnant or are breast-feeding, you must tell your doctor, nurse or pharmacist, before receiving MenQuadfi.

3. What if I am taking other medicines?

Some medicines may interfere with MenQuadfi and may affect how it works. Tell your doctor, nurse or pharmacist if

• You are taking, have recently taken or might take any other vaccines or medicines, including any medicines,

vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

 You have been treated with medicines that may affect your body's natural defenses (immune system) such as high-dose corticosteroids or chemotherapy. Your response to vaccines may not be optimal.

For age appropriate situations, MenQuadfi can be given at a separate injection site during the same visit with other vaccines. Your doctor will advise you if MenQuadfi is to be given at the same time as another vaccine.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MenQuadfi.

4. How do I use MenQuadfi?

How much is given

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

5. What should I know after using MenQuadfi?

Things you should do

Call your doctor straight away if you:

Notice signs of allergic reaction which include rash, itching, difficulty breathing, shortness of breath or swelling of the face, lips, throat or tongue.

Driving or using machines

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

Looking after your medicine

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

- keep it where young children cannot reach it.
- keep MenQuadfi 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 MenQuadfi.

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

Do not use MenQuadfi if the packaging is torn or shows signs of tampering.

Getting rid of unwanted Medicine

Medicines including vaccines 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.

6. Are there any side effects?

All medicines including vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 In children 12 – 23 months of age tenderness, redness or swelling where the injection was given feeling irritable crying loss of appetite feeling drowsy fever vomiting diarrhoea 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 In persons 2 years of age and older pain, redness, swelling, itching, warmth, bruising or rash where the injection was given muscle pain headache feeling unwell fever vomiting feeling dizzy nausea fatigue 	

Serious side effects

Ser	ious side effects	What to do
٠	Allergic reaction-related:	Call your
	∘ rash	doctor
	 itching 	straight away
	 difficulty breathing, 	or go straight
	 shortness of breath 	to the
	 swelling of the face, lips, 	Emergency
	throat, or tongue	Department
 Fits (convulsions) with or without fever 		at your
		nearest
		hospital if you
		notice any of
		these serious
		side effects.

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u> in Australia or in New xZealand at

https://pophealth.my.site.com/carmreportnz/s/.

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

7. Product details

This vaccine is only available with a doctor's prescription.

What MenQuadfi contains

Active ingredients (main ingredients)	10 micrograms of each meningococcal polysaccharide groups A, C, Y and W-135 joined to approximately 55 micrograms of tetanus toxoid
Other ingredients (inactive ingredients)	Sodium chloride, sodium acetate and water for injections

Do not use this vaccine if you are allergic to any of these ingredients.

What MenQuadfi looks like

MenQuadfi is a clear, colourless solution for injection.

MenQuadfi is available in packs of 1 or 10 single dose (0.5 mL) vials. Not all pack sizes may be marketed.

AUST R 325682

Who distributes MenQuadfi

Distributed in Australia by: sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113 Freecall: 1800 818 806 Email: <u>medinfo.australia@sanofi.com</u> Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics PO Box 62027 Sylvia Park Auckland 1644 Freecall: 0800 283 684

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