Package leaflet: Information for the user

Menveo powder and solution for solution for injection
Meningococcal Group A, C, W-135 and Y conjugate vaccine

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

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

1. What Menveo is and what it is used for

Menveo is a vaccine that is used for active immunization of children (from 2 years of age), adolescents and adults at risk of exposure to a bacterium named *Neisseria meningitidis* serogroups A, C, W-135 and Y, to prevent invasive disease. The vaccine works by causing your body to make its own protection (antibodies) against these bacteria.

Neisseria meningitidis serogroup A, C, W-135 and Y bacteria can cause serious and sometimes life-threatening infections such as meningitis and sepsis (blood poisoning).

Menveo cannot cause bacterial meningitis. This vaccine contains a protein (called CRM_{197}) from the bacteria that cause diphtheria. Menveo does not protect against diphtheria. This means that you (or your child) should receive other vaccines to protect against diphtheria when these are due or when advised by your doctor.

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

Do not use Menveo if you or your child has:

- ever had an allergic reaction to the active substances or any of the other ingredients of this vaccine (listed in section 6)
- ever had an allergic reaction to diphtheria toxoid (a substance used in a number of other vaccines)
- an illness with high fever. However, a mild fever or upper respiratory infection (for example cold) itself is not a reason to delay vaccination.

Warnings and precautions:

Talk to your doctor or nurse before you or your child are given Menveo if you or your child:
- have a weakened immune system. Little is known about the effectiveness of Menveo when administered to individuals with weakened immunity due to the use of immunosuppressive medications, or HIV infection, and other possible causes. It is possible that the effectiveness of Menveo could be reduced in such individuals.
- have haemophilia or any other problem that may stop your blood from clotting properly, such as persons receiving blood thinners (anticoagulants).
- receive treatment that blocks the part of the immune system known as complement activation, such as eculizumab. Even if you have been vaccinated with Menveo you remain at increased risk of disease caused by the *Neisseria meningitidis* groups A, C, W-135 and Y bacteria.

Fainting, feeling faint or other stress-related reactions can occur as a response to any needle injection. Tell your doctor or nurse if you have experienced this kind of reaction previously.

This vaccine can only protect against meningococcal group A, C, W-135, and Y bacteria. It cannot protect against other types of meningococcal bacteria other than groups A, C, W-135 and Y, or against other causes of meningitis and sepsis (blood poisoning).

As with any vaccine, Menveo may not fully protect 100% of those who get the vaccine.

If you or your child received a dose of Menveo more than one year ago and remains at particular risk of exposure to meningococcal group A bacteria, consideration may be given to administering a booster dose to maintain protection. Your doctor will advise you if and when you should receive a booster dose.

Other medicines and Menveo

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Menveo may be given at the same time as other vaccinations but any other injected vaccines should preferably be given into a different arm from the site of the Menveo injection.

These include the following vaccines: tetanus, reduced diphtheria and acellular pertussis (Tdap), human papillomavirus (HPV), yellow fever, typhoid fever (Vi polysaccharide), Japanese encephalitis, rabies, hepatitis A and B and meningococcal group B (Bexsero).

Menveo's effect could be diminished when administered to individuals who are taking medicines that suppress the immune system.

Separate injection sites must be used if more than one vaccine is being administered at the same time.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before this medicine is given. Your doctor or nurse may still recommend that you receive Menveo if you are at high risk of infection with meningococcal group A, C, W-135 and Y bacteria.

Driving and using machines

Menveo 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.

Menveo contains

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
This medicinal product contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

3. How to use Menveo

Menveo will be given to you or your child by a doctor or nurse.

The vaccine is usually given into the upper arm muscle (deltoid) for children (from 2 years of age), adolescents and adults. Your doctor or nurse will take care to ensure the vaccine is not given into a blood vessel and will make sure that it is injected into muscle and not into the skin.

For children (from 2 years of age), adolescents and adults: a single (0.5 mL) injection will be given.

The safety and efficacy of Menveo in children under 2 years of age has not yet been established. There are limited data in individuals aged 56-65 and there are no data in subjects aged older than 65 years.

Please tell your doctor if you have received a previous injection with Menveo or another meningococcal vaccine. Your doctor will tell you if you need an additional injection of Menveo.

For information on the reconstitution of the vaccine see the section for medical or healthcare professionals at the end of this leaflet.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects reported during clinical studies usually lasted only one to two days and were not usually severe.

The following side effects may happen after receiving Menveo:

Very common (may affect more than 1 in 10 people): headache, muscle ache, irritability (in children from 2 to 10 years of age), generally feeling unwell, injection site pain, injection site redness (≤ 50 mm), injection site firmness (≤ 50 mm).

Common (may affect up to 1 in 10 people): fever (≥ 38 °C), vomiting (in children from 2 to 10 years of age), diarrhoea (in children from 2 to 10 years of age), nausea, chills, change in eating habits (in children from 2 to 10 years of age), sleepiness (in children from 2 to 10 years of age), joint ache, rash, injection site redness (> 50 mm), injection site firmness (> 50 mm)

Uncommon (may affect up to 1 in 100 people): allergic reactions, fainting, dizziness (in adolescents from 11 years of age and adults), balance disorder, enlarged lymph nodes, injection site itching, injection site swelling

Very rare (may affect up to 1 in 10 000 people): fits (convulsions) including fits associated with fever, infection of the skin at the injection site, extensive swelling of the injected limb

Not known (cannot be estimated from the available data): severe allergic reactions that manifest with the following symptoms: swelling of the lips, mouth, throat (which may cause difficulty in

swallowing), difficulty breathing with wheezing or coughing, rash and swelling of the hands, feet and ankles, loss of consciousness, very low blood pressure.

If a severe allergic reaction occurs tell your doctor straight away or go immediately/ take your child to the nearest Accident and Emergency department because urgent medical help may be needed.

Reporting of side effects
If you 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Menveo

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the vials in the outer carton in order to protect from light.

After reconstitution, the product should be used immediately. However, chemical and physical stability after reconstitution was demonstrated for 8 hours below 25 °C.

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will dispose of this medicine. These measures will help protect the environment.

6. Contents of the pack and other information

What Menveo contains

One dose (0.5 mL of the reconstituted vaccine) contains:
The active substances are:

(Originally contained in the powder)

• Meningococcal group A oligosaccharide	10 micrograms
Conjugated to *Corynebacterium diphtheriae* CRM_{197} protein	16.7 to 33.3 micrograms

(Originally contained in the solution)

• Meningococcal group C oligosaccharide	5 micrograms
Conjugated to *Corynebacterium diphtheriae* CRM_{197} protein	7.1 to 12.5 micrograms
• Meningococcal group W-135 oligosaccharide	5 micrograms
Conjugated to *Corynebacterium diphtheriae* CRM_{197} protein	3.3 to 8.3 micrograms
• Meningococcal group Y oligosaccharide	5 micrograms
Conjugated to *Corynebacterium diphtheriae* CRM_{197} protein	5.6 to 10.0 micrograms

The other ingredients (excipients) are:

In the powder: potassium dihydrogen phosphate and sucrose.

In the solution: sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydrogen phosphate dihydrate and water for injection (See also end of section 2).

What Menveo looks like and contents of the pack

Menveo is a powder and a solution for injection.
Each dose of Menveo is supplied as a:
- 1 Vial containing the MenA Lyophilised Conjugate Component as a white to off-white powder
- 1 Vial containing the MenCWY Liquid Conjugate Component as clear solution
- Pack size of one dose (2 vials), five doses (10 vials) or ten doses (20 vials). Not all pack sizes may be marketed.

The contents of the two components (vial and vial) are to be mixed prior to vaccination providing 1 dose of 0.5 mL.

Marketing Authorisation Holder

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name Menveo powder and solution for solution for injection
Reference number 19494/0289
This is a service provided by the Royal National Institute of Blind People.

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The following information is intended for healthcare professionals only:

Reconstitution of the vaccine

Menveo must be prepared for administration by reconstituting the powder with the solution.

The contents in the two different vials (MenA powder and MenCWY solution) are to be mixed prior to vaccination providing 1 dose of 0.5 mL.

Using a syringe and suitable needle (21G, 40 mm length or 21 G, 1 ½ inch length), withdraw the entire contents of the vial of solution and inject into the vial of powder to reconstitute the MenA conjugate component.

Invert and shake the vial vigorously and then withdraw 0.5 mL of reconstituted product. Please note that it is normal for a small amount of liquid to remain in the vial following withdrawal of the dose. Prior to injection, change the needle with one suitable for the administration. Ensure that no air bubbles are present in the syringe before injecting the vaccine.

Following reconstitution, the vaccine is a clear, colourless to light yellow solution, free from visible foreign particles. In the event of any foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine.

Menveo is given as an intramuscular injection, preferably into the deltoid muscle.

Any unused product or waste material should be disposed of in accordance with local requirements.