

MENVEO

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 or pharmacist.

1. Why am I receiving MENVEO?

MENVEO is a vaccine used for the active immunisation of children (from the age of 2 months), adolescents and adults to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y. *Neisseria meningitidis* can cause meningitis, a very serious disease.

For more information, see Section [1. Why am I receiving MENVEO?](#) in the full CMI.

2. What should I know before I receive MENVEO?

Do not use if you have ever had an allergic reaction to MENVEO, diphtheria toxoid (used in other vaccines) or any of the ingredients listed at the end of the CMI.

Talk to your doctor 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 receive MENVEO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MENVEO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I receive MENVEO?

- Your doctor or nurse will give you MENVEO as an injection into your upper arm or upper thigh muscle (for children under 2 years of age).

More instructions can be found in Section [4. How do I receive MENVEO?](#) in the full CMI.

5. What should I know after receiving MENVEO?

Things you should do	<ul style="list-style-type: none">Keep a record of your immunisation history.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how MENVEO affects you.
Looking after your medicine	<ul style="list-style-type: none">MENVEO will normally be stored at the doctor's surgery or in the pharmacy.If you need to store MENVEO, keep it in the refrigerator between 2°C and 8°C. Do not freeze.

For more information, see Section [5. What should I know after receiving MENVEO?](#) in the full CMI.

6. Are there any side effects?

Side effects which have been reported following administration of MENVEO include redness, firmness and/or pain at the injection site, injection site itching, inflammation including swelling of the injected limb, enlarged lymph nodes near the injection site, tiredness, sore throat, rash, headaches, muscle aches, joint aches, fever, chills, a general feeling of being unwell, nausea, impaired hearing, ear pain, spinning sensation.

Allergic reactions have also occurred following administration of MENVEO. Allergy is rare and severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.

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.

MENVEO

Active ingredient(s): meningococcal (groups A, C, W-135 and Y) oligosaccharide CRM₁₉₇ conjugate vaccine

Consumer Medicine Information (CMI)

This leaflet provides important information about MENVEO.

You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about receiving MENVEO.

Where to find information in this leaflet:

- [1. Why am I receiving MENVEO?](#)
- [2. What should I know before I receive MENVEO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive MENVEO?](#)
- [5. What should I know after receiving MENVEO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving MENVEO?

MENVEO is a vaccine used for active immunisation of children (from the age of 2 months), adolescents and adults to prevent invasive disease caused by Neisseria meningitidis serogroups A, C, W-135 and Y.

Meningitis is an infection of the spinal fluid and the tissues that surround the brain. Of the microbes that cause meningitis, one of the most severe is Neisseria meningitidis (meningococcus). Meningococcal meningitis is an infectious disease that is spread from person to person. It is a very serious disease and is sometimes fatal. It can cause permanent physical and neurological damage.

MENVEO can only protect you or your child from meningitis caused by four groups of Neisseria meningitidis (A, C, W-135 and Y). It will not protect you or your child from meningitis caused by other groups of Neisseria meningitidis or from meningitis caused by different kinds of microbes.

MENVEO works by causing your body to produce its own protection (antibodies) against meningococcal bacteria. Your body usually takes a couple of weeks after vaccination to develop protection against Neisseria meningitidis.

If a vaccinated person comes into contact with Neisseria meningitidis, the body is usually able to destroy it. However, as with all vaccines, 100% protection cannot be guaranteed.

Sometimes individuals may react unfavourably to the vaccine. The chance of a severe reaction from MENVEO is very small but the risks from not being vaccinated against meningococcal disease may be very serious.

2. What should I know before I receive MENVEO?

Warnings

Do not receive MENVEO if:

- you are allergic to MENVEO or any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can use this medicine.

- you have ever had an allergic reaction to diphtheria toxoid (a substance used in other vaccines)
- you have a very high fever

In this case your vaccination with MENVEO may have to be delayed. Discuss this with your doctor or nurse before you receive MENVEO.

- you have had an allergic reaction or become unwell after receiving another meningococcal vaccine
- you have a severe infection with a high temperature

A minor infection such as a cold should not be a problem however talk to your doctor or nurse about this before being vaccinated.

Check with your doctor if you:

- have any other medical conditions including any that involve your immune system
- have a low blood platelet count
- 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 can remain at increased risk of disease caused by Neisseria meningitidis groups A, C, W-135 and Y.

- take any medicines for any other condition
- have an allergy to latex
- have had an allergic reaction after any other vaccination. Symptoms include difficulty breathing, swelling of the throat, fits (convulsions) including fits associated with fevers, high fevers and severe reactions at the injection site.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

They will discuss with you the benefits and risks of receiving MENVEO during pregnancy or whilst breastfeeding.

Fainting

Fainting can occur following, or even before, any needle injection. Tell the person giving you your injection if you or your child have ever fainted with a previous injection.

3. What if I am taking other medicines?

Tell your doctor or nurse if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MENVEO and affect how it works.

Tell your doctor or nurse if you or your child have had any vaccines recently.

MENVEO may be given at the same time as other vaccinations.

Other vaccines must be injected into a different arm or leg (for children aged 2-23 months) from the site of the MENVEO injection. These include:

- tetanus, reduced diphtheria and acellular pertussis vaccine
- human papillomavirus vaccine

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

4. How do I receive MENVEO?

How much is given

- Your doctor or nurse will give you MENVEO as an injection
- The dose is 0.5 mL

How is it given

- MENVEO is injected into your upper arm or for children under 2 years of age into the thigh muscle
- It should not be injected directly into a blood vessel

If you are given too much MENVEO

If you think that you have been given too much MENVEO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after receiving MENVEO?

Things you should do

- keep a record of your vaccination history

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MENVEO affects you.

Looking after your medicine

- MENVEO will usually be stored at the doctor's clinic or at the pharmacy.
- If you need to store MENVEO it is important to keep it in the refrigerator between 2°C and 8°C in the original pack.
- Do not freeze MENVEO.
- Following reconstitution and in order to reduce microbiological hazard, MENVEO should be used as soon as practicable after reconstitution. If storage is necessary, keep MENVEO in the refrigerator between 2°C and 8°C for no more than 24 hours.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

The vials left over after administration of MENVEO must be disposed of as medical waste.

6. Are there any side effects?

All medicines 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 or nurse if you have any further questions about side effects.

Your doctor or nurse might ask you to remain for observation following vaccination.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • redness, firmness and/or pain at the injection site • injection site itching, inflammation including swelling of the injected limb • enlarged lymph nodes near the injection site • tiredness • sore throat • rash • headaches • muscle aches, joint aches • fever, chills, a general feeling of being unwell • nausea • impaired hearing, ear pain, spinning sensation 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • allergic reaction <p>Signs of an allergic reaction include: swelling of the limbs, face, eyes, inside of the nose, mouth or throat shortness of breath, breathing or swallowing difficulties hives, itching (especially of the hands or feet), reddening of the skin (especially around the ears) or severe skin reactions unusual tiredness or weakness that is sudden and severe</p> <p>Allergy to MENVEO is rare. Severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.</p> <ul style="list-style-type: none"> • falls, head injury • bone pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> dizziness, balance disorder fainting, seizures facial nerve paralysis, upper eyelid fall raised bumps of fluid on the skin increased liver enzymes in blood test results 	

Tell your doctor or nurse 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 www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or nurse before you decide to stop taking any of your medicines.

7. Product details

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

What MENVEO contains

Active ingredient (main ingredient)	MenA vial: Meningococcal oligosaccharide group A Men CWY vial: Meningococcal oligosaccharide group C Meningococcal oligosaccharide group W135 Meningococcal oligosaccharide group Y
Other ingredients (inactive ingredients)	MenA vial: <ul style="list-style-type: none"> monobasic potassium phosphate sucrose MenCWY vial: <ul style="list-style-type: none"> dibasic sodium phosphate dihydrate monobasic sodium phosphate monohydrate sodium chloride water for injections

MENVEO does not contain lactose, gluten, thiomersal (organic mercurial), tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What MENVO looks like

Each dose of MENVEO is made up of 2 vials:

- Vial containing the MenA lyophilised conjugate component as a white to off-white powder

- Vial containing the MenCWY liquid conjugate component as a clear solution

The contents of both vials (MenA vial and MenCWY vial) are mixed prior to vaccination.

MENVEO is available as either a single dose (2 vials) pack or a 5 dose (10 vials) multipack (AUST R 192696).

Not all presentations and pack sizes may be marketed.

Who distributes MENVEO

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

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