

Menomune[®]

Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined

Consumer Medicine Information

What is in the leaflet

This leaflet answers some common questions about MENOMUNE[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having MENOMUNE[®] against the benefits they expect it will have. **If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist. Keep this leaflet.** You may need to read it again.

What MENOMUNE[®] is used for

MENOMUNE[®] is a vaccine used to help prevent meningitis or infections caused by the meningococcal bacteria groups A, C, Y and W-135. MENOMUNE[®] is used to help prevent meningitis in people likely to be infected with the meningococcal bacteria. These include:

- travellers to countries where there is a risk of contracting meningitis
 - people living in an area where an outbreak or epidemic of meningitis has occurred
 - people in close contact with someone who has meningitis
 - people at high-risk of contracting meningitis such as those who have their spleen removed or their spleen does not work properly
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How MENOMUNE[®] works

MENOMUNE[®] works by causing your body to produce its own protection against infections caused by meningococcal bacteria groups A, C, Y and W-135. It does this by making substances called antibodies in the blood which fight meningococcal bacteria. If a vaccinated person comes into contact with meningococcal bacteria groups A, C, Y and W-135, the body is usually ready to destroy it. Your body usually takes several weeks after vaccination to develop protection against the meningococcal bacteria. Protection requires one dose. Most people will produce enough antibodies against meningococcal bacteria groups A, C, Y and W-135. However, as with all vaccines, 100% protection cannot be guaranteed.

MENOMUNE[®] will not protect you against bacteria other than meningococci groups A, C, Y and W-135. The vaccine will not give you or your child meningitis. The chance of a severe reaction from MENOMUNE[®] is very small, but the risks from not being vaccinated against meningitis may be very serious.

Before you are given MENOMUNE[®]

If you are not sure whether you or your child should have MENOMUNE[®] talk to your doctor or pharmacist.

WHEN YOU OR YOUR CHILD MUST NOT BE GIVEN MENOMUNE[®]

Do not have MENOMUNE[®] if you have allergies to MENOMUNE[®] or any of the ingredients listed at the end of this leaflet..

Do not have MENOMUNE® if you have a current illness.

Your doctor may decide to delay vaccination until the illness has passed. MENOMUNE® is not recommended for use in children 2 years and under.

Do not have MENOMUNE® after the expiry date printed on the pack.

Do not have MENOMUNE® if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have MENOMUNE®, talk to your doctor or pharmacist.

BEFORE YOU OR YOUR CHILD ARE GIVEN MENOMUNE®

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- lowered immunity due to diseases such as malaria, HIV/AIDS or cancer
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)
- leukaemia or any other cancers of the blood or lymph system
- your spleen is removed or your spleen does not work properly

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having MENOMUNE® during pregnancy.

Tell your doctor if you are breastfeeding.

Your doctor will discuss the possible risks and benefits of having MENOMUNE® during breastfeeding.

TAKING OTHER MEDICINES

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

Some medicines and MENOMUNE® may interfere with each other. These include:

- medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

These medicines may be affected by MENOMUNE® or may affect how well it works. (You may need different amounts of these medicines, or you may need to take different medicines.) Your doctor or pharmacist will advise you and decide whether or not to give the vaccine.

HAVING OTHER VACCINES

Tell your doctor if you have had any vaccines in the last 4 weeks.

Your doctor will advise you if MENOMUNE® is to be given with another vaccine.

Some vaccines should not be given at the same time as MENOMUNE®. These include:

- whole-cell pertussis vaccine, a vaccine used to help prevent infection by the pertussis bacteria which causes whooping cough
- whole-cell typhoid vaccine, a vaccine used to help prevent infection by the typhoid bacteria

These vaccines and MENOMUNE® contain endotoxin, which is a bacterial product. If these vaccines are given at the same time as MENOMUNE®, the combined amount of endotoxin from these vaccines may cause side effects.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with MENOMUNE®.

How MENOMUNE® is given

MENOMUNE® is given as a single injection, usually into your upper arm by a doctor or nurse. MENOMUNE® should not be injected directly into the veins, muscle or skin.

HOW MUCH IS GIVEN

Usually one injection of MENOMUNE® is given.

Follow all directions given to you by your doctor carefully.

Overdose is unlikely as your doctor is giving you the injection.

If you have any concerns, ask your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well after having Menomune®. MENOMUNE® may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- local reaction around the injection site such as tenderness and redness of the skin
- headaches
- tiredness, weakness or fatigue
- generally feeling unwell
- high temperature (more than 38°C)

These are the more common side effects of MENOMUNE®. Mostly these are mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- shortness of breath, wheezing or trouble breathing
- headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.

Storing MENOMUNE®

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

- Keep it where children cannot reach it.
 - Keep MENOMUNE® in the original pack until it is time for it to be given.
 - Keep it in the refrigerator, between 2°C and 8°C. Do not freeze MENOMUNE®. Freezing destroys the vaccine.
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Product Description

What MENOMUNE® looks like

Each pack of MENOMUNE® contains one vial of vaccine powder and one syringe of liquid. Your doctor will inject the liquid into the vial to make the liquid for your injection. The resulting liquid is a clear colourless liquid.

Ingredients

Active ingredients:

- 50 micrograms of polysaccharide from each of the group A, C, Y and W-135 *Neisseria meningitidis*.

Other ingredients:

- Sodium chloride solution
- Lactose

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Further Information

MENOMUNE® is available only with a doctor's prescription.

Ask your doctor if you are unsure about anything or want more information about MENOMUNE®.

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