Mencevax ACWY®

Meningococcal polysaccharide groups A, C, Y and W135 vaccine

Powder and solvent for solution for injection, monodose

Date : June, 2016. Version 1.

Belgium, MRP.

UAE, Lebanon & Jordan

PACKAGE LEAFLET

Package leaflet: Information for the user

Mencevax ACWY powder and solvent for solution for injection
Meningococcal polysaccharide groups A, C, Y and W_{135} vaccine

Read all of this leaflet carefully before you or your child start receiving this vaccine 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 or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mencevax ACWY is and what it is used for

Mencevax ACWY is a vaccine used in children older than 2 years, adolescents and adults to prevent disease caused by the bacteria named "*Neisseria meningitidis* groups A, C, W_{135} and Y". These bacteria are highly contagious and can cause serious and sometimes life-threatening infections such as meningitis (infection around the brain or spinal cord) or septicaemia (blood poisoning). These diseases may be followed by permanent disabilities.

The vaccine works by causing the body to produce its own protection (antibodies) against these bacteria.

This vaccine contains purified parts of the bacteria *Neisseria meningitidis* (groups A, C, W_{135} and Y). None of the components in the vaccine are infectious.

Mencevax ACWY will only protect against infections caused by the *Neisseria meningitidis* groups A, C, W_{135} and Y for which the vaccine has been developed.

As with all vaccines, Mencevax ACWY may not fully protect all people who are vaccinated.

2. What you need to know before you or your child receive Mencevax ACWY

Mencevax ACWY should not be given
- if you or your child are allergic (hypersensitive) to the active substances or any of the other ingredients of Mencevax ACWY (listed in section 6).
- if you or your child have previously had an allergic reaction to any vaccine against *Neisseria meningitidis* group A, C, W_{135} or Y.
- if you or your child have a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.

Do not have Mencevax ACWY if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having this vaccine.

Warnings and precautions
Talk to your doctor or pharmacist before you or your child receive Mencevax ACWY

Persons with a weakened immune system, for example due to HIV infection or due to medicines that suppress the immune system, may not get the full benefit from Mencevax ACWY.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you or your child fainted with a previous injection.

If you or your child remain at increased risk of invasive meningococcal disease, re-vaccination may be needed in accordance with available official recommendations.

Other medicines and Mencevax ACWY
Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

If necessary, Mencevax ACWY can be administered at the same time as other vaccines. The other injectable vaccines should always be administered at a different injection site.

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 or pharmacist for advice before taking this medicine.

Driving and using machines
Mencevax ACWY may cause drowsiness or dizziness. If you are affected do not drive or use machinery.

Mencevax ACWY contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium free”.

3. How Mencevax ACWY is given

You or your child will receive a single dose of 0.5 ml.

If you remain at risk of infection it may be necessary to have another dose. Your doctor will advise you on re-vaccination.

The doctor will give Mencevax ACWY as an injection deep under the skin.

The vaccine should never be given into a vein or in the skin.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
After commercialisation of Mencevax ACWY, some people had a serious allergic reaction to the vaccine. These may be local or widespread skin rash that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness. **If these occur, you should contact a doctor urgently.**

Joint pain, muscle stiffness, hives, rash and flu-like symptoms such as high temperature, sore throat, runny nose, cough and chills have also been reported after commercialisation of the vaccine.

Side effects that occurred during clinical trials with Mencevax ACWY were as follows:

Very common (these may occur with more than 1 in 10 doses of the vaccine):
- Pain, redness or tenderness at the injection site
- Headache
- Fatigue
- Irritability
- Feeling drowsy

Common (these may occur with up to 1 in 10 doses of the vaccine):
- Swelling or hard lump at the injection site
- Loss of appetite
- Gastrointestinal symptoms e.g. nausea, vomiting and diarrhoea
- Fever

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- Dizziness
- Decreased feeling or sensitivity in the skin
- Numbing, bruising at the injection site

Reporting of side effects
If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly according to their local requirements. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mencevax ACWY

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 carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Store in the original package in order to protect from light.

After reconstitution, the vaccine should be used immediately. However, chemical and physical in-use stability has been demonstrated for 8 hours at 2-8°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you or your child no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mencevax ACWY contains

- The active substances are:

Neisseria meningitidis group A polysaccharide	50 µg
Neisseria meningitidis group C polysaccharide	50 µg
Neisseria meningitidis group Y polysaccharide	50 µg
Neisseria meningitidis group W_{135} polysaccharide	50 µg

- The other ingredients are:
  Powder: sucrose, trometamol
  Solvent: sodium chloride, water for injections

What Mencevax ACWY looks like and contents of the pack

Powder and solvent for solution for injection.
The powder is white. The solvent is clear and colourless.

Both components must be mixed together before you or your child receive the vaccine. The mixed appearance is a clear and colourless liquid.

Mencevax ACWY is available in packs of:
- 1 vial of powder and 1 vial of solvent for 1 dose (0.5 ml)
- 100 vials of powder and 100 vials of solvent for 1 dose (0.5 ml)
- 1 vial of powder and 1 ampoule of solvent for 1 dose (0.5 ml)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer S.A., Boulevard de la Plaine 17, 1050 Brussels, Belgium

Manufactured by:
GlaxoSmithKline Biologicals SA, 89, rue de l'Institut, 1330 Rixensart, Belgium

This leaflet was last revised in June 2016.

To report any side effect(s):	
United Arab Emirates (UAE): Pharmacovigilance and Medical Device Section P.O. Box 1853 Tel: 80011111 Email: pv@moh.gov.ae Drug Department Ministry of Health & Prevention Dubai	**Lebanon :** Website :www.moph.gov.lb
Jordan: Website : www.jfda.jo Tel: 0096265632000 - 0096264602550 Fax:0096265105916 - 0096265105893 E-mail : info@jfda.jo	