

MENCEVAX[®] ACWY

Meningococcal ACWY vaccine

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about MENCEVAX ACWY vaccine.

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 being given MENCEVAX ACWY vaccine against the benefits they expect it will have for you.

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 MENCEVAX ACWY VACCINE IS USED FOR

MENCEVAX ACWY is a vaccine used to help prevent (meningococcal) meningitis. Meningitis occurs when bacteria (most commonly *Neisseria meningitidis*) infect the tissue lining the brain. Meningitis can be a highly infectious disease which is sometimes fatal.

Please note that MENCEVAX ACWY can

only protect you from meningitis caused by the four groups of *Neisseria meningitidis* (A, C, W and Y). It will not protect you from meningitis caused by other agents.

How it works

MENCEVAX ACWY works by causing your body to produce its own protection (or antibodies), against the meningococcal bacteria. If a vaccinated person comes into contact with *Neisseria meningitidis*, the body is usually ready to destroy it. This protection can last for at least three years.

Most people will produce enough antibodies to protect against meningococcal disease. However, as with all vaccines, 100% protection cannot be guaranteed.

Your body usually takes a couple of weeks after vaccination to develop protection against *Neisseria meningitidis*.

MENCEVAX ACWY can be used in adults and children over two years of age. Vaccination is recommended for the following:

- Persons who are in close contact of patients with meningococcal disease
- Persons who intend to travel to areas where the disease is common (eg South America and Africa)

- Persons who have certain diseases or conditions that make them more susceptible to a meningococcal infection or who may develop serious problems from such an infection (eg. persons who lack a functioning spleen)
- To control outbreaks of infection in confined communities.

MENCEVAX ACWY may also be prescribed for other persons or situations. **Please talk to your doctor if you have any questions.**

MENCEVAX ACWY is not recommended for infants or children under two years of age. The vaccine may not be effective in this age group.

The chance of a severe reaction from MENCEVAX ACWY vaccine is very small, but the risks from not being vaccinated against meningococcal disease may be very serious.

BEFORE YOU ARE GIVEN MENCEVAX ACWY VACCINE

Do Not Have Mencevax ACWY If:

- you/your child have had an allergic reaction to MENCEVAX ACWY, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

If you/your child have had MENCEVAX ACWY before and became unwell, tell your doctor, nurse or pharmacist before the next dose is given.

- you/your child have had an allergic reaction or became unwell after receiving any other meningococcal vaccine (eg. Menomune)
- you/your child have a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor, nurse or pharmacist about this before being vaccinated.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

If you are not sure whether you/your child should have MENCEVAX ACWY, talk to your doctor, nurse or pharmacist. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you/your child.

Before You Receive MENCEVAX ACWY:

Tell your doctor or pharmacist if you have/your child has allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have/your child has reacted to previous vaccination, including:

- life-threatening allergic reaction
- difficulty breathing
- swelling of the throat
- fainting or collapse
- shock-like state or being unresponsive for a long period of time
- fits or convulsions
- high temperature (*greater than 40°C*)
- crying or screaming lasting for more than 3 hours
- severe skin reaction at the injection site.

Tell your doctor if you have/your child has an infection or high temperature.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

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

- an immune deficiency condition
- malaria.

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

Your doctor will discuss the possible risks and benefits of receiving MENCEVAX ACWY vaccine during pregnancy.

Tell your doctor if you are breastfeeding.

Your doctor will discuss the possible risks and benefits of receiving MENCEVAX ACWY vaccine during breastfeeding.

Taking other medicines

The response of some vaccines may be affected if other medicines or vaccines are used at the same time. You should therefore inform your doctor if you are using other medicines regularly or have had another vaccine recently. Your doctor will be able to tell you if any problems could occur with the use of MENCEVAX ACWY and other medicines or vaccines.

Tell your doctor if you have had/your child has had any vaccine in the last 4 weeks.

HOW MENCEVAX ACWY VACCINE IS GIVEN

The doctor or nurse will give MENCEVAX ACWY vaccine as an injection. The vaccine is injected under the skin (subcutaneously). **If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.**

MENCEVAX ACWY should never be given intravenously. How much is given

You/your child will receive one dose (0.5 mL) of the vaccine.

Vaccination may need to be repeated after 2-3 years if you/your child remains at risk of infection.

AFTER HAVING MENCEVAX ACWY VACCINE

Things you must do:

Keep a record of you/your child's vaccinations, and update this after each injection/dose.

Keep your follow-up appointments with your doctor or clinic.

If required, it is important to have your follow-up doses of MENCEVAX ACWY vaccine at the appropriate times to make sure the vaccine has the best chance of providing protection against meningococcal disease.

Things to be careful of:

Be careful driving or operating machinery until you know how MENCEVAX ACWY vaccine affects you.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not/your child does not feel well after receiving MENCEVAX ACWY vaccine.

MENCEVAX ACWY vaccine 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 may need medical treatment if you get some of the side effects.

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

Most unwanted side effects with MENCEVAX ACWY are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

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, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- redness, itchiness or swollen lymph glands at the injection site
- swelling around the armpit
- flushing or redness of the skin
- headaches
- dizziness
- tiredness, weakness or fatigue
- generally feeling unwell

These side effects are usually mild.

As with all vaccines given by injection there is a very small risk of serious allergic reaction. If any of the

following happen, tell your doctor or pharmacist immediately or go to the Accident and Emergency Department at your nearest hospital:

- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
- unusual tiredness or weakness that is sudden and severe.

These are very serious side effects that usually occur within the first few hours of vaccination. You/your child may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Tell your doctor if you notice any of the following:

- fever (greater than 38°C) and/or chills
- neurological reactions (reactions involving the nervous system).

These reactions are rare but can be serious.

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

Do not be alarmed by this list of possible side effects.

You/your child may not experience any of them.

STORAGE

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

- **keep it where children cannot reach it**
- **keep it in the refrigerator. It can also be frozen if necessary**
- **keep MENCEVAX ACWY vaccine in the original pack until it is time for it to be given.**

The salt solution that comes with the vaccine should be kept at room temperature.

PRODUCT DESCRIPTION

What it looks like

MENCEVAX ACWY comes as a white, dry powder either as a single dose (AUST R 42486) or multi dose (AUST R 42487).

The salt solution is clear and colourless.

Ingredients

Each 0.5 mL dose of MENCEVAX ACWY contains 50 micrograms of polysaccharide from each of the four groups of *Neisseria meningitidis* contained in the vaccine.

The vaccine also contains lactose.

The salt solution provided with the mono-dose vaccine contains sodium chloride. The salt solution provided with the multi-dose vaccine

contains sodium chloride and phenol.

MENCEVAX ACWY vaccine does not contain sucrose, gluten, tartrazine or any other azo dyes.

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

MENCEVAX ACWY is only available if prescribed by a doctor.

Manufacturer

GlaxoSmithKline Biologicals
Rixensart, Belgium

Distributor

GlaxoSmithKline Australia Pty
Ltd
1061 Mountain Highway
Boronia VIC 3155

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