

NIMENRIX®

Meningococcal polysaccharide serogroups A, C, W-135 and Y conjugate vaccine
powder and solvent for solution for injection in pre-filled syringe

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you have NIMENRIX.

This leaflet answers some common questions about NIMENRIX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All vaccines and medicines have risks and benefits. Your doctor has weighed the expected benefits of you or your child having NIMENRIX against the possible risks.

If you have any questions about NIMENRIX, ask your doctor, nurse or pharmacist.

Keep this leaflet. You may need to read it again.

What NIMENRIX is used for

NIMENRIX is a vaccine used to help prevent meningococcal disease, caused by four types of *Neisseria meningitidis* bacteria (types A, C, W and Y).

NIMENRIX works by causing your body to produce its own protection (or antibodies), against these types of meningococcal bacteria. NIMENRIX cannot cause meningococcal disease.

The most common types of meningococcal disease are meningitis (infection of a lining around the brain and spinal cord) and

septicaemia (blood infection).

Neisseria bacteria can less commonly infect the joints, lungs or other organs.

Meningococcal disease is spread by small droplets from the nose, mouth or throat. Meningococcal Disease is generally serious and sometimes causes long-term effects (eg deafness, memory problems, loss of fingers or toes), or death.

As with all vaccines, NIMENRIX may not protect all people who are vaccinated.

Also, NIMENRIX does not help to protect against meningococcal disease caused by other types of *Neisseria*, or meningitis caused by other bacteria or viruses.

NIMENRIX can be used in adults and children over 12 months of age, and is particularly recommended for:

Travellers to countries where meningococcal A, W or Y disease outbreaks may happen (eg parts of Africa, annual Hajj)

Close contacts of people with meningococcal A, W or Y disease

People with medical conditions that make them more likely to get meningococcal disease (eg. people without a functioning spleen or some people with a poor immune response to infections).

NIMENRIX may also be prescribed for other people or situations.

Ask your doctor if you have any questions about why NIMENRIX has been prescribed for you or your child.

Before you or your child has NIMENRIX

Do not have NIMENRIX if:

- You or your child has had an allergic reaction to NIMENRIX, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you or your child have had NIMENRIX before and became unwell, tell your doctor or nurse before the vaccine is given.

- You or 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 or nurse before having the vaccine.

- The expiry date printed on the NIMENRIX pack has passed
- The NIMENRIX packaging is torn or shows signs of tampering.

Before having NIMENRIX, tell your doctor or nurse if:

- **You or your child have had a serious reaction to any vaccine, including.**
 - an allergic reaction
 - difficulty breathing
 - swelling of the throat
 - fainting or collapse
 - shock-like state or being unresponsive
 - fits or convulsions
 - high temperature (greater than 40°C)
 - severe skin reaction at the injection site
 - crying or screaming lasting for more than 3 hours, in a child.
- **You or your child have allergies to:**
 - any medicines
 - any other substances, such as foods, preservatives or dyes.
- **You or your child fainted with a previous vaccine.**

Fainting can occur following, or even before any needle injection.

- **You or your child have these medical conditions:**
 - low platelets or a bleeding disorder, since bleeding can occur after injection of NIMENRIX.
 - You or your child have any condition, treatment or medicines that affect the immune response to infections.
- You or your child may still have NIMENRIX if your doctor or nurse recommends it, but may not be protected as much as other people.
- **You are pregnant, plan to become pregnant or are breastfeeding.**

Your doctor will discuss the possible risks and benefits of having

NIMENRIX during pregnancy or breastfeeding.

- **You or your child have had a vaccine in the last 4 weeks, or have recently taken any medicines, including medicines that don't need a prescription.**

Some vaccines may be affected by other vaccines or medicines. Your doctor, pharmacist or nurse will be able to tell you what to do.

NIMENRIX can be given at the same time as these vaccines: hepatitis A and hepatitis B; diphtheria, tetanus, pertussis (DTPa), including combination DTPa vaccines containing hepatitis B, inactivated polio (IPV) or *Haemophilus influenzae* (Hib); measles-mumps-rubella (MMR) vaccine, including in combination with varicella (MMRV); seasonal flu and a pneumococcal vaccine.

If you have not told your doctor or nurse about any of the above, tell him or her before you or your child has NIMENRIX.

How NIMENRIX is given

HOW IS IT GIVEN

Your doctor or nurse will give NIMENRIX as an injection. The vaccine is injected into muscle (intramuscularly), usually in the arm for children and adults.

WHEN IS IT GIVEN

Most people will have one NIMENRIX injection.

Some people at increased or continued risk of meningococcal infection may have two initial NIMENRIX injections, NIMENRIX after another meningococcal vaccine, and/or a booster dose of NIMENRIX every 5 years.

Your doctor will advise if you or your child need more than one NIMENRIX injection.

IF YOU OR YOUR CHILD MISS A DOSE

If a dose of NIMENRIX is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

If you have any questions about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

IF YOU TAKE TOO MUCH (overdose)

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia) or the National Poisons Centre on 0800 764 766 (0800 POISON) (New Zealand). When you or your child have NIMENRIX

THINGS YOU MUST DO

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

Keep any follow-up visits with your doctor or clinic. If required, it is important for you or your child to have follow-up doses of NIMENRIX 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 NIMENRIX affects you. In some people, vaccination can cause dizziness or lightheadedness.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child does not feel well after receiving NIMENRIX.

NIMENRIX, like all medicines and vaccines, may cause unwanted side effects in some people. Most of the time side effects are not serious; however, sometimes they may need medical treatment.

Do not be alarmed by the following lists of side effects. You or your child may not experience any of them.

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

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

Tell your doctor or nurse if you notice any of the following side effects and they worry you:

Very common (may occur in more than 1 in 10 people)

- pain, redness or swelling around the injection site
- loss of appetite
- fever
- drowsiness or feeling tired
- headache
- irritability in a child

Common (may occur in up to 1 in 10 people)

- diarrhoea, vomiting or nausea
- bruising at the injection site

Uncommon (may occur in up to 1 in 100 people)

- warmth, itchiness, lack of sensation, or a hard lump around the injection site
- dizziness
- trouble sleeping

- decreased sensation or itchiness of the skin; rash
- pain in a muscle, arm or leg
- feeling unwell
- crying in a child

Rare (may occur in up to 1 in 1000 people)

- large swelling of the vaccinated limb associated with redness

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction. This usually happens within hours, but may occur days to weeks after vaccination.

If any of the following happen, tell your doctor or nurse 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.

This is not a complete list of side effects for NIMENRIX. Others may occur in some people, and there may be some side effects not yet known.

Tell your doctor, nurse or pharmacist if you notice any side effects not listed above.

Storage

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

- In the fridge, stored between 2°C and 8°C.

- Do NOT freeze NIMENRIX, store it in the bathroom, or leave it in the car.
- In the original pack, to protect it from light.
- Out of reach of children.

Ask your pharmacist what to do with NIMENRIX that has expired or not been used.

Product description

WHAT IT LOOKS LIKE

NIMENRIX comes as a white powder in a vial, together with a pre-filled syringe or glass container of clear liquid (solvent). The powder is dissolved in the solvent by the doctor or nurse, just before injection.

INGREDIENTS

NIMENRIX contains agents that stimulate an immune response to *Neisseria meningitidis* types A, C, W and Y.

The vaccine also contains sucrose and trometamol.

The solvent contains sodium chloride (salt) and water for injection.

NIMENRIX vaccine does not contain lactose, gluten, tartrazine or any other azo dyes.

Further information

NIMENRIX is only available if prescribed by a doctor.

Pharmaceutical companies are not in the position to give people medical advice. Your doctor or pharmacist is the best person to give you advice on vaccination.

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