NIMENRIX®

Meningococcal polysaccharide groups A, C, W-135 and Y conjugate vaccine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you or your child are given 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 (e.g. 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 infants from 6 weeks of age, children and adults.

NIMENRIX may also be prescribed for other people or situations.

If you are not sure whether you or your child should be given this vaccine, talk to your doctor.

Before you or your child is given NIMENRIX

WHEN NIMENRIX SHOULD NOT BE GIVEN:

- **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 been given NIMENRIX before and became unwell, tell your doctor or nurse before the vaccine is given.

- **You or your child has 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 BEING GIVEN 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 the following vaccines:

Infants from 6 weeks up to 12 months of age:

Combined diphtheria, tetanus, acellular pertussis (DTaP), hepatitis B, inactivated poliovirus (IPV) and Haemophilus influenzae type b (Hib) vaccines and 10-valent pneumococcal conjugate vaccine.

Children from 12 months of age and adults:

Hepatitis A and hepatitis b vaccines; DTaP vaccines, including combination DTaP vaccines with hepatitis B, IPV or Hib; measles-mumps-rubella (MMR) vaccine, including in combination with varicella (MMRV); seasonal flu and 10 or 13 valent pneumococcal conjugate vaccines; human papillomavirus bivalent vaccine (HPV2) and diphtheria toxoid and acellular pertussis vaccine (Tdap) in individuals aged 9 to 25 years.

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

How NIMENRIX is given

HOW IT IS GIVEN

Your doctor or nurse will give NIMENRIX as an injection. The vaccine is injected into muscle, usually in the thigh for babies from 6 to 12 weeks of age.

In children from 12 months of age and adults, NIMENRIX can be injected into the thigh or arm muscle.

WHEN IT IS GIVEN

Infants 6 weeks to less than 6 months of age:

Your baby will receive two doses, with the first dose given from 6 weeks of age, and a 2 month interval before the second dose. A third (booster) dose is recommended at 12 months of age.

Infants 6 months to less than 12 months of age:

Your baby will receive one dose given from 6 months of age. A booster dose is recommended at 12 months of age, with an interval of at least 2 months after the initial dose.

Children from 12 months of age and adults:

Most people will be given one NIMENRIX injection.

Some people at increased or continued risk of meningococcal infection may be given two initial NIMENRIX injections; NIMENRIX after another meningococcal vaccine; and/or a booster dose of NIMENRIX.

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 National Poisons Centre on 0800 764 766 (0800 POISON) (New Zealand).

When you or your child are given 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 be given 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 light headedness.

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:

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/fussiness in a child

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

- diarrhoea, vomiting or nausea
- bruising at the injection site
- rash (in infants)

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
- 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.

Tell your doctor, nurse or pharmacist if you notice anything else that is making you or your child feel unwell.

Other side effects not listed above may occur in some people.

There may also be some side effects not yet known.

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 2ºC and 8ºC.**
- **store it in the original pack, to protect it from light.**
- **keep it out of reach of children.**

Do not freeze NIMENRIX, store it in the bathroom, or leave it in the car.

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.

Supplier

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.

NIMENRIX is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland, New Zealand

Toll Free number: 0800 736 363

This leaflet was prepared in November 2019.

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