



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Nimenrix (*meningococcal group A, C, W-135 and Y conjugate vaccine*)

An overview of Nimenrix and why it is authorised in the EU

### What is Nimenrix and what is it used for?

Nimenrix is a vaccine used to protect adults, adolescents and children from the age of 6 weeks against invasive meningococcal disease caused by four groups of the bacterium *Neisseria meningitidis* (group A, C, W-135, and Y). Invasive disease occurs when the bacteria spread through the body causing serious infections such as meningitis (infection of the membranes that surround the brain and spine) and septicaemia (blood poisoning).

The vaccine contains substances from the outer coat of the bacterium *N. meningitidis*.

### How is Nimenrix used?

Nimenrix can only be obtained with a prescription and should be used according to available official recommendations. It is available as a powder and solvent that are mixed together to make a solution for injection. The powder is available in a vial, and the solvent is available in a pre-filled syringe or in an ampoule (a sealed container).

Nimenrix is given as an injection into the thigh or shoulder muscle. In infants from 6 weeks to less than 6 months of age, two doses of Nimenrix are recommended (the first dose is given from 6 weeks of age, the second dose 2 months afterwards). Children from 6 months of age, adolescents and adults should be given one dose of Nimenrix, but an additional dose may be considered for some children at high risk of invasive meningococcal disease (at least 2 months after the last dose of Nimenrix).

Children who received the initial dose (or doses) of Nimenrix between 6 weeks and one year of age should receive a booster dose at 1 year of age, at least 2 months after the last dose of Nimenrix.

Nimenrix may also be used as a booster vaccine in people from 1 year of age who have already been vaccinated with another meningococcal vaccine, to reinforce the level of protection.

For more information about using Nimenrix, see the package leaflet or contact your doctor or pharmacist.

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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## How does Nimenrix work?

Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a specific disease. When a person is given the vaccine, the immune system recognises the parts of the bacterium in the vaccine as 'foreign' and makes antibodies against them. When the person comes into contact with the bacterium, these antibodies, together with other components of the immune system, will be able to kill the bacteria and help protect against the disease.

Nimenrix contains small amounts of capsular polysaccharides (sugars from the outer coat) extracted from the four groups of the *N. meningitidis* bacterium: A, C, W135 and Y. These have been purified and then 'conjugated' (attached) to a protein carrier called tetanus toxoid (a weakened toxin of tetanus which does not cause disease, also used in tetanus vaccine), because this improves the immune response to the vaccine.

## What benefits of Nimenrix have been shown in studies?

The ability of Nimenrix to trigger the production of antibodies (immunogenicity) was assessed in five main studies involving over 4,000 participants aged 1 year or more. Nimenrix was compared with several other similar vaccines against *N. meningitidis*. Results showed that a single injection of Nimenrix was as effective as the other vaccines in stimulating an immune response against all four types of *N. meningitidis* polysaccharides. The number of people who had an immune response against the polysaccharides with Nimenrix was similar to the other vaccines.

Studies also showed that, in people vaccinated with Nimenrix or another meningococcal vaccine when they were 1 year of age or older, Nimenrix given as a booster several years after they had been vaccinated increased the level of antibodies.

A sixth study in over 2,000 children first vaccinated between 6 and 12 weeks of age showed that Nimenrix (given as 2 doses 2 months apart) was as effective as two other vaccines against *N. meningitidis* in stimulating an immune response. Based on data from this study and additional data from a supporting study in 187 infants, this dose of Nimenrix was also considered to be effective in children between 12 weeks and less than 6 months of age. For children between 6 months and one year of age, the available data allowed to conclude that a single dose of Nimenrix was sufficient to stimulate an immune response against *N. meningitidis*.

## What are the risks associated with Nimenrix?

The most common side effects from initial vaccination with Nimenrix (which may affect more than 1 patient in 10) are loss of appetite, irritability, drowsiness, headache, fever, swelling, pain and redness at the site of injection, and tiredness. Side effects after booster vaccination with Nimenrix are generally similar to those after initial vaccination, but diarrhoea, vomiting and nausea are also very common. For the full list of side effects and restrictions of Nimenrix, see the package leaflet.

## Why is Nimenrix authorised in the EU?

The European Medicines Agency considered that Nimenrix had been shown to be at least as effective as comparable vaccines at stimulating an immune response to the four groups of the *N. meningitidis* bacterium in people of different age groups. The Agency noted that Nimenrix offered the benefits of conjugated vaccines over conventional vaccines, including producing a strong immune response in young children. Nimenrix is well tolerated and the Agency considered that it can be safely given together with other routinely used vaccines in the different age groups. Therefore, the Agency decided

that the benefits of Nimenrix are greater than its risks and recommended that it be granted marketing authorisation.

### **What measures are being taken to ensure the safe and effective use of Nimenrix?**

The company that markets Nimenrix will carry out a study to assess how long the protective immune response provided by one or two doses of Nimenrix lasts in young children between 1 and 2 years old.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nimenrix have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nimenrix are continuously monitored. Side effects reported with Nimenrix are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Nimenrix**

Nimenrix received a marketing authorisation valid throughout the EU on 20 April 2012.

Further information on Nimenrix can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/nimenrix](http://ema.europa.eu/medicines/human/EPAR/nimenrix).

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