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MenQuadfi® (active substance: *Neisseria meningitidis* group A, C, W-135 and Y polysaccharides conjugated to tetanus toxoid carrier protein)

First authorisation in Switzerland: 5 October 2022

Medicinal product (vaccine) for active immunisation against invasive meningococcal disease in children from 12 months of age and adults

About the medicine

The active substance in the vaccine MenQuadfi comprises polysaccharides from groups *A, C, W-135* and *Y* of *Neisseria meningitidis* which are bound to the tetanus toxoid carrier protein. MenQuadfi is available as a ready-to-use solution for injection in single doses.

MenQuadfi is a quadrivalent vaccine used for the prevention of (active immunisation against) invasive meningococcal disease caused by groups A, C, W and Y of the *Neisseria meningitidis* bacteria.

Meningococcal disease is a rare infectious disease that can develop rapidly, often in people who were previously healthy. The purulent inflammation of the meninges and the sepsis that can be caused by meningococci are among the most widely feared diseases. In many cases, meningococcal disease is associated with complications.

Meningococcal disease usually has a rapid course and may have a fatal outcome. Between 10% and 20% of survivors suffer from long-term complications.

Mode of action

The active substance in MenQuadfi comprises elements of the disease-causing pathogen (saccharides from the meningococcal capsule) . The active substance stimulates the natural defence mounted by the body's immune system and leads to the human body forming antibodies against the bacteria *Neisseria meningitidis* serogroups A, C, W and Y (active immunisation). Bonding the active substance to the carrier protein enhances the immunisation.

Together with other components of the immune system, the antibodies formed after

vaccination can combat the bacteria more effectively and provide protection against meningococcal disease caused by *N. meningitidis* bacteria serogroups A, C, W and Y.

For detailed explanations of the mode of action of vaccines, we recommend the Swissmedic videos on vaccines.

Use

The vaccine MenQuadfi is available as a solution for injection in vials containing single doses. One dose (0.5 ml) contains 10 micrograms each of the *Neisseria meningitis* polysaccharides of groups A, C, Y and W-135.

MenQuadfi is injected into the shoulder muscle or a specific part of the thigh muscle.

MenQuadfi should be used in accordance with the official vaccination recommendations.

Basic immunisation for children aged 12 months and older and adults consists of a single dose (0.5 ml). A single dose of MenQuadfi (0.5 ml) can be used for booster immunisation. There are no data to determine the need and timing of a booster vaccination with MenQuadfi.

If patients have an acute and severe feverish disease, the doctor should postpone vaccination. If the infection is mild, however, the patient can still be vaccinated.

It may not be possible to achieve adequate protection through vaccination in patients whose immune system is weakened or suppressed as a result of disease or treatment. MenQuadfi provides protection only against *Neisseria meningitidis* from groups A, C, W and Y. The vaccine does not provide protection against other groups of *Neisseria meningitidis*.

Efficacy

The efficacy of basic immunisation of children aged 12 months and older and adults was investigated in 6 studies.

In deciding whether to approve the authorisation request for the vaccine MenQuadfi, Swissmedic took into account the assessment of the European Medicines Agency (EMA) regarding certain aspects such as the clinical data on individuals aged 2 years and older, as well as the corresponding product information.

The assessment of efficacy and safety by Swissmedic concentrated on toddlers under 2 years of age. The efficacy and safety of MenQuadfi in toddlers between 12 and 23 months of age were investigated in the pivotal study MET51 and the supporting study MET54. Study MET57 investigated the safety and immunogenicity of simultaneous administration of MenQuadfi with other paediatric vaccines.

Study MET51 was a modified double-blind, randomised, multi-centre trial in toddlers aged 12 to 23 months who had either not been vaccinated against meningococci or had been vaccinated with a monovalent meningococcal C vaccine during infancy. The results of study MET51 showed that the immune response (efficacy) of MenQuadfi 30 days after vaccination is not inferior to the comparator vaccine.

Study MET54 was a randomised, open Phase 2 study in 200 healthy toddlers aged 12 to 23 months who had not been vaccinated with meningococcal vaccines.

The study evaluated the immune response and the safety profile of a single dose of MenQuadfi compared to that of a quadrivalent vaccine that is available in Europe but not authorised in Switzerland.

Study MET62 investigated antibody persistence following initial vaccination and the antibody response to booster vaccination with MenQuadfi in children aged 4–5 years who had received a single dose of MenQuadfi or the comparator vaccine three years previously at the age of 12–23 months in study MET54.

The studies performed demonstrated the efficacy (active immunisation) of the vaccine MenQuadfi in preventing meningococcal disease caused by *Neisseria meningitidis* from groups A, C, W and Y.

Precautions, undesirable effects & risks

MenQuadfi must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all vaccines, MenQuadfi can also produce side effects, although not necessarily in everyone. The most common adverse reactions are headache, pain or swelling at the injection site, fatigue, irritability, loss of appetite and muscle pain (myalgia).

As with all vaccines, an anaphylactic reaction (acute allergic reaction) can occur following the administration of MenQuadfi. Therefore, the doctor should monitor patients after vaccination and, if necessary, initiate medical measures.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The submitted clinical documentation on the efficacy and safety of MenQuadfi with the additionally provided study results were considered appropriate to support the authorisation of MenQuadfi for active immunisation of individuals aged 12 months and older against meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y.

The efficacy demonstrated in the studies performed documents protection against meningococcal disease caused by *Neisseria meningitidis* groups A, C, W and Y.

Taking all the risks and precautions into account, and based on the available data, the benefits of MenQuadfi outweigh the risks.

Swissmedic has therefore authorised the vaccine MenQuadfi with the active substance polysaccharides of *Neisseria meningitidis* groups *A, C, W-135* and *Y* for Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Fachinformation MenQuadfi.

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated in the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.