Summary of the Risk Management Plan (RMP) for MENQUADFI®

MENQUADFI® (MENINGOCOCCAL POLYSACCHARIDE (SEROGROUPS A, C, W-135 AND Y) TETANUS TOXOID CONJUGATE VACCINE)

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Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them. The RMP summary of MENQUADFI® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le medicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization. Please note that the reference document which is valid and relevant for the effective and safe use of Adacel® in Switzerland is the "Arzneimittelinformation/ Information sur le medicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Sanofi-aventis (suisse) sa is fully responsible for the accuracy and correctness of the content of this published summary RMP of MENQUADFI®.

1. THE MEDICINE AND WHAT IT IS USED FOR

According to Swiss label

MenQuadfi is authorised for active immunization of individuals from the age of 12 months and older, against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y.

The use of this vaccine should be in accordance with available official recommendations.

According to EU SmPC

MenQuadfi is authorised for active immunization of individuals from the age of 12 months and older, against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y. The use of this vaccine should be in accordance with available official recommendations (see SmPC for the full indication). It contains 10 µg of each of the meningococcal polysaccharide serogroups A, C, W and Y as the active substance and it is given by intramuscular route, preferably in the deltoid region or anterolateral thigh depending on the recipient's age and muscle mass.

Further information about the evaluation of MenQuadfi's benefits can be found in MenQuadfi's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/menquadfi

2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of MenQuadfi, together with measures to minimise such risks and the proposed studies for learning more about MenQuadfi's risks, are outlined in the next sections.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment so that

immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of MenQuadfi is not yet available, it is listed under 'missing information' outlined in the next section.

2.1. List of important risks and missing information

Important risks of MenQuadfi are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of MenQuadfi. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table 1 List of important risks and missing information

Important identified risks	None
Important potential risk	None
Missing information	Long-term persistence of the vaccine response, and safety and immunogenicity of booster in individuals primed with MenQuadfi Co-administration with MenB vaccine Use during pregnancy

2.2. Summary of important risks

Table 2 Important risks and missing information with corresponding risk minimisation a ctivities minimisation activities and additional pharmacovigilance activities if any

Missing information: Long term persistence of the vaccine response, and safety and immunogenicity of booster in individuals primed with MenQuadfi	
Risk minimization measures	**Routine risk minimisation measures** SmPC Section 5.1 **Additional risk minimisation measures** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities** Booster study in children (MET62) Booster study in adolescents and adults (MET59) Booster study in older adults (MEQ00066) See Section VI.2.3 of this summary for an overview of the post-authorisation development plan
Missing information: Co-administration with MenB vaccine	
Risk minimization measures	**Routine risk minimisation measures** SmPC section 4.5

	Additional risk minimisation measures None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities** Booster study in adolescents and adults (MET59) Safety, immunogenicity and co-administration with MenB vaccine study in infants and toddlers (MET52) See Section VI.2.3 of this summary for an overview of the post-authorisation development plan
Missing information: Use during pregnancy	
Risk minimization measures	**Routine risk minimisation measures** SmPC Section 4.6 **Additional risk minimisation measures** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities** Pregnancy registry (MEQ00070) See Section VI.2.3 of this summary for an overview of the post-authorisation development plan

2.3. Post-authorisation development plan

2.3.1 Studies which are conditions of the marketing authorization

The following study is conducted as a condition of the marketing authorization:

Table 3 – Studies which are conditions of the marketing authorization

Booster study in children (MET62)
Purpose of the study: This study evaluates the safety and immunogenicity of a single dose of MenQuadfi in children in Finland who had been vaccinated 3 years earlier as toddlers at 12 to 23 months of age with either MenQuadfi or Nimenrix®. In addition, this study evaluates the antibody persistence following the primary dose of MenQuadfi.
Booster study in adolescents and adults (MET59)
Purpose of the study: This study evaluates the safety and immunogenicity of a single dose of MenQuadfi in adolescents and adults ≥ 13 to < 26 years of age in The United States who had been vaccinated 3-6 years earlier with either MenQuadfi or Menveo®. In addition, this study evaluates the antibody persistence following the primary dose of MenQuadfi. This study will also evaluate the immunogenicity and safety of a booster dose of MenQuadfi when given concomitantly with the first dose of a Meningococcal serogroup B vaccine.
Booster study in older adults (MEQ00066)

Purpose of the study: This study evaluates the safety and immunogenicity of a single dose of MenQuadfi in subjects in the United States who received a dose of Menomune® or MenQuadfi≥ 3 years previously, at ≥ 56 years of age. In addition, this study evaluates the antibody persistence following the primary dose of MenQuadfi.

2.3.2 Other studies in post-authorisation development plan

Table 4 - Others studies in post-authorisation development plan

Safety, immunogenicity and co-administration with MenB vaccine study in infants and toddlers (MET52)
Purpose of the study: This study evaluates the safety and immunogenicity of MenQuadfi when administered concomitantly with a meningococcal serogroup B vaccine (Bexsero®) and other routine pediatric vaccines as part of the National Immunization Schedule in healthy infants and toddlers in the UK.
Pregnancy registry (MEQ00070)
Purpose of the study: This study assesses maternal, obstetrical, pregnancy, and neonatal and infant outcomes among women vaccinated with MenQuadfi during pregnancy or in the 30 days preceding their last menstrual period or estimated date of conception

REFERENCES

None