**WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

**MenQuadfi™**

**Meningococcal Polysaccharide (Serogroups A, C, W, and Y) Tetanus Toxoid Conjugate Vaccine**

**Sanofi Pasteur, Inc., USA**

## What is MenQuadfi™?

MenQuadfi™ is a clear, colorless solution of Meningococcal Polysaccharide (Serogroups A, C, W, and Y) Tetanus Toxoid Conjugate Vaccine presented in a single dose glass vial.

Each dose of vaccine (0.5 mL) contains:

| **Active components and quantity per dose** | |
|---|---|
| Meningococcal (Serogroup A) Polysaccharide (Monovalent Conjugate) | 10 µg |
| Meningococcal (Serogroup C) Polysaccharide (Monovalent Conjugate) | 10 µg |
| Meningococcal (Serogroup Y) Polysaccharide (Monovalent Conjugate) | 10 µg |
| Meningococcal (Serogroup $W_{135}$) Polysaccharide (Monovalent Conjugate) | 10 µg |
| Tetanus Toxoid, Filtered Concentrate | 55 µg* |
| **Excipients** | |
| Sodium Chloride (within 1.675% Sodium Chloride solution) | 3.35 mg, tonicity adjuster (0.675%) |
| Sodium Acetate (within 50mM Sodium Acetate, pH 6.0 Solution) | 1.23 mg (30mM), pH adjuster |

* Tetanus toxoid quantity is approximate and dependent on the polysaccharide to protein ratio for the conjugates used in each formulation.

MenQuadfi™ comes in packs of 1 and 5 vials. Each vaccine vial consists of 1 dose of 0.5 mL of vaccine. The vaccine should be administered by intramuscular injection only, preferably in the deltoid region or anterolateral thigh depending on the recipient's age and muscle mass.

MenQuadfi™ is filled in a Type I USP borosilicate glass vial. The vials closure system is complemented with a stopper of chlorobutyl, secured by a flip-off aluminium seal.

The stability data submitted by the prequalification holder supports a shelf life of 48 months when the vaccine is stored between 2°C to 8°C. The vaccine should be shipped and stored at this recommended temperature, and it should not be frozen. The data provided support the use of VVM 14 and if required it will be part of the vaccine label.

MenQuadfi™ is manufactured at a Sanofi Pasteur, Inc. at Discovery Drive, Swiftwater, PA 18370, USA.

**What is MenQuadfi™ used for?**

MenQuadfi™ is indicated 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, as recommended by WHO (WHO position paper November 2011).

**How is MenQuadfi™ used?**

MenQuadfi™ should be administered as a single 0.5mL injection intramuscularly.

Primary vaccination

- Individuals 12 months of age and older: One single dose (0.5 mL).

Booster Vaccination

- A single dose of MenQuadfi™ maybe administered to individuals 15 years of age and older who are at continued risk of meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (group A, C, W, Y) conjugate vaccine.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

MenQuadfi™ should not be used if visible particulate matter and/or discoloration are present in the solution.

**What are the vaccine characteristics?**

MenQuadfi™ must be stored as recommended by manufacturer, between 2°C to 8°C. Under these recommended storage conditions, the vaccine is stable for 48 months from the date of manufacture.

The vaccine does not contain preservative.

Cold chain volume per dose is 54 $cm^3$/dose in the secondary carton of 1 vial.

**Who is the regulatory authority responsible for its oversight vis a vis WHO?**

The European Medicines Agency (EMA) is the Regulatory Authority of record for the WHO prequalification procedure. The Marketing Authorization (MA) for MenQuadfi™ was issued by the US FDA on 23 April 2020 and the EMA CHMP positive recommendation was issued on 18 November 2020.

**How has MenQuadfi™ been studied from the clinical point of view?**

The vaccine was studied in eleven (pivotal and supportive) completed Phase I, Phase II, and Phase III studies in infants, toddlers, children, adolescents, and adults (including those 56 years of age and older) conducted in Spain, Hungary, Finland, Germany, Australia, Canada, US, Puerto Rico, Mexico, Russian Federation, South Korea, and Thailand were included in this dossier. In six of the seven pivotal studies, antibody response of MenQuadfi was compared to different comparators (Nimenrix, Menveo, Menactra, Menomune) in different age groups from toddlers of 12 - 23 months to adults ≥56 years. In all these studies the primary objective to demonstrate non-inferiority of MenQuadfi against the comparator vaccine was met for all serogroups. The overall safety database of MenACYW consists of 7116 subjects. 6398 subjects received the final MenACYW formulation in the 9 pivotal studies included in the safety analysis, thereof 5417 alone and 981 subjects with a concomitant vaccine. Out of the 5417 subjects exposed to MenACYW, there were 691 toddlers, 492 children (2 through 9 years), 1897 adolescents, 1684 adults, 298 older adults (56 to 64 years), and 349 elderly adults (65

years and above). The safety profile was comparable to the currently available licensed MCV4 vaccines Menveo, Menactra, and Nimenrix.

**Other information about evaluation of MenQuadfi™**

Evaluation of MenQuadfi™ application was supported by the evaluation reports provided by the European Medicines Agency (EMA). This included the final assessment reports conducted by the Agency and the positive opinion of the CHMP on granting the marketing authorization of the vaccine.

The vaccine prequalification dossier was submitted in a CTD format. The vaccine meets WHO WHO Technical Report Series (e.g., TRS 962, Annex 2 “Recommendations to assure the quality, safety and efficacy of group A meningococcal conjugate vaccines”). In addition, the vaccine was found in compliance with WHO programmatic suitability criteria and UN specific labelling requirement.

This summary was accepted on August 2022 and publish on September 2022.