Professional Information for MenQuadfi

SCHEDULING STATUS:

S4

1. NAME OF THE MEDICINE

MenQuadfi (solution for injection)

Meningococcal (Groups A, C, Y, W) Polysaccharide Tetanus Toxoid Conjugate Vaccine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per 0,5 mL **dose:**

Active substance:

Neisseria meningitidis group A polysaccharide[1]	10 micrograms
Neisseria meningitidis group C polysaccharide[1]	10 micrograms
Neisseria meningitidis group Y polysaccharide[1]	10 micrograms
Neisseria meningitidis group W polysaccharide[1]	10 micrograms
[1]Conjugated to tetanus toxoid carrier protein	55 micrograms

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MenQuadfi is indicated for active immunisation 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.

4.2 Posology and method of administration

Posology

Primary vaccination:

- Individuals 12 months of age and older: One single dose (0,5 mL).

Booster vaccination:

- A single 0,5 mL dose of MenQuadfi may be used to boost subjects who have previously received a meningococcal vaccine containing the same serogroups (see section 5.1).
- Long-term antibody persistence data following vaccination with MenQuadfi are available up to 7 years after vaccination (see sections 4.4 and 5.1).

Other paediatric population

The safety and immunogenicity of MenQuadfi in individuals under 12 months of age have not yet been established.

Method for administration

For intramuscular injection only, preferably in the deltoid region or anterolateral thigh depending on the recipient's age and muscle mass.

For instructions on handling of the vaccine before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or after previous administration of the vaccine or a vaccine containing the same components.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

MenQuadfi should not be administered subcutaneously, intravascularly or intradermally.

It is good clinical practice to precede vaccination by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable effects) and a clinical examination.

Hypersensitivity

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

Intercurrent illness

Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, should not result in the deferral of vaccination.

Syncope

Syncope (fainting) and other anxiety-related reactions can occur following or even before any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling or injury and to manage syncope.

Thrombocytopenia and coagulation disorders

MenQuadfi should be given with caution to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration.

Protection

MenQuadfi will only protect against *Neisseria meningitidis* groups A, C, W, and Y. The vaccine will not protect against any other *Neisseria meningitidis* groups.

As with any vaccine, vaccination with MenQuadfi may not protect all vaccine recipients.

Waning of serum bactericidal antibody titres against serogroup A when using human complement in the assay (hSBA) has been reported for MenQuadfi and other quadrivalent meningococcal vaccines. The clinical relevance of this observation is unknown. However, if an individual is expected to be at particular risk of exposure to serogroup A and received a dose of MenQuadfi more than approximately one year previously, consideration may be given to administering a booster dose.

Lower hSBA geometric mean titres (GMTs) against serogroup A have been observed after a single dose of MenQuadfi was administered to toddlers who previously received serogroup C meningococcal conjugate vaccine (MenC-CRM) during infancy. Nevertheless, seroprotection rates were comparable between treatment groups (see section 5.1). The clinical relevance of this observation is unknown. This aspect might be. considered for individuals at high risk for MenA infection who received MenC-CRM vaccine in their first year of life.

Immunodeficiency

It may be expected that in patients receiving immunosuppressive persons treatment or patients with immunodeficiency, an adequate immune response may not be elicited (see section 4.5). Persons with familial complement deficiencies (for example, C5 or C3 deficiencies) and receiving treatments that inhibit terminal complement activation (for example, eculizumab) are at increased risk of invasive disease caused by *Neisseria meningitidis* groups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi. No data on immunocompromised patients are available.

Tetanus immunisation

Immunisation with MenQuadfi vaccine does not substitute for routine tetanus immunisation. Co-administration of MenQuadfi with a tetanus toxoid-containing vaccine does not impair the response to tetanus toxoid or impact the safety.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dose that is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction

Use with other vaccines

Injection sites on separate limbs and separate syringes must be used in the case of concomitant administration.

For ages 12 – 23 months, MenQuadfi can be co-administered with the measles-mumps-rubella vaccine (MMR) and varicella vaccine (V), combined diphtheria - tetanus - acellular pertussis (DTaP) vaccines, including combination DTaP vaccines with hepatitis B (HBV), inactivated poliovirus (IPV) or *Haemophilus influenzae* type b (Hib) such as DTaP-IPV-HB-Hib (Hib conjugated to tetanus toxoid) vaccine and 13-valent pneumococcal polysaccharide conjugated vaccine (PCV-13).

For ages 10 – 17 years, MenQuadfi can be co-administered with diphtheria, tetanus, pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (Tdap) and human papillomavirus vaccine (recombinant, adsorbed) (HPV).

There was no impact on the immune response to MenQuadfi when a meningococcal serogroup B vaccine was co-administered.

MenQuadfi can be administered concomitantly with PCV-13. Lower hSBA GMTs on day 30 post-dose for serogroup A has been observed when given concomitantly. The clinical relevance of this observation is unknown. As a precaution in children 12 – 23 months of age at high risk for serogroup A disease, consideration might be given for administration of MenQuadfi and PCV-13 vaccines separately.

Meningococcal vaccine naïve children aged 10 – 17 years had non inferior response for PT and

lower antibody responses to FHA, PRN and FIM when Tdap vaccine was administered concomitantly with MenQuadfi and HPV compared to co-administration with HPV vaccine alone. The clinical implications of the observed pertussis antigen responses also observed with the existing quadrivalent meningococcal conjugate vaccines are unknown.

Concomitant vaccines should always be administered at separate injection sites and preferably contralateral.

Concomitant administration of MenQuadfi and other vaccines than those listed above has not been studied.

Use with systemic immunosuppressive medicinal products

It may be expected that in patients receiving immunosuppressive treatment an adequate immune response may not be elicited (see also section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited amount of data on the use of MenQuadfi in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). MenQuadfi should be used during pregnancy only if the expected benefits for the mother outweigh the potential risks, including those for the foetus.

Breastfeeding

It is unknown whether MenQuadfi is excreted in human milk. MenQuadfi should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Fertility

A developmental and reproductive toxicity study was performed in female rabbits. There were no effects on mating performances or female fertility. No study was conducted on male fertility (see

section 5.3).

4.7 Effects on ability to drive and use machines

MenQuadfi has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

The safety of a single dose of MenQuadfi in individuals 12 months of age and older was evaluated in seven randomized, active-controlled, multi-centre pivotal studies. In these studies, 6 308 subjects received either a primary dose (N=5 906) or a booster dose (N=402) of MenQuadfi and were included in the safety analyses. This included 1 389 toddlers aged 12 through 23 months of age, 498 children aged 2 through 9 years, 2 289 adolescents aged 10 through 17 years, 1 684 adults aged 18 through 55 years, 199 older adults aged 56 through 64 years, and 249 elderly aged 65 years and older. Of these, 392 adolescents received MenQuadfi co-administered with Tdap and HPV, and 589 toddlers received MenQuadfi co-administered with MMR+V (N=189), DTaP-IPV-HB-Hib (N=200) or PCV-13 (N=200).

The most frequently reported adverse reactions within 7 days after vaccination with a single dose of MenQuadfi alone in toddlers 12 through 23 months of age were irritability (36,7 %) and injection site tenderness (30,6 %) and in ages 2 years and above were injection site pain (38,7 %) and myalgia (30,5 %). These adverse reactions were mostly mild or moderate in intensity.
Rates of adverse reactions after a booster dose of MenQuadfi in adolescents and adults at least 15 years of age were comparable to those seen in adolescents and adults who received a primary dose of MenQuadfi.

Rates of adverse reactions within 7 days following vaccination among or toddlers were comparable when MMR+V were given concomitantly with without MenQuadfi, and when DTaP-IPV-HB-Hib was

given with or without MenQuadfi. Overall, the rates of adverse reactions were higher in toddlers who received PCV-13 given concomitantly with MenQuadfi (36,5 %) than in toddlers who received PCV-13 alone (17,2 %).

In one additional clinical study, adolescents and adults 13 – 26 years of age primed with MenQuadfi 3 – 6 years previously received MenQuadfi co-administered with meningococcal serogroup B (MenB) vaccine, Trumenba (N=93) or Bexsero (N=92).
Rates and intensity of systemic reactions within 7 days following vaccination tended to be higher when MenQuadfi was given concomitantly with MenB vaccine than when MenQuadfi was given alone. The most common solicited systemic reaction was myalgia, of mild intensity, which was experienced more frequently in adolescents and adults who received MenQuadfi and MenB vaccine concomitantly (Trumenba, 65,2 %; Bexsero, 63 %) compared to those who received MenQuadfi alone (32,8 %).

Tabulated list of adverse reactions

The following adverse reactions, as listed below, have been identified from clinical studies conducted with MenQuadfi when given alone to subjects 2 years of age and older. The safety profile observed in toddlers aged 12 through 23 months is presented in the paediatric population section.

The adverse reactions are listed according to the following frequency categories:
Very common (≥1/10);
Common (≥1/100 to <1/10);
Uncommon (≥1/1 000 to <1/100);
Rare (≥1/10 000 to <1/1 000).
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1: Tabulated summary of adverse reactions following administration of MenQuadfi from clinical trials in subjects 2 years of age and above.

MedDRA System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Rare	Lymphadenopathy
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
Gastrointestinal disorders	Uncommon	Vomiting, nausea
	Rare	Diarrhoea, stomach pain
Skin and subcutaneous tissue disorders	Rare	Urticaria, pruritus, rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia
	Rare	Pain in extremity
General disorders and administration site conditions	Very common	Malaise
		Injection site pain
	Common	Fever
		At the injection site: swelling, erythema
	Uncommon	Fatigue
		At the injection site: pruritus, warmth, bruising, rash
	Rare	Chills, axillary pain
		At the injection site: induration

Paediatric population

The safety profile of MenQuadfi in children and adolescents 2 through 17 years of age was generally comparable to that in adults. Injection site erythema and swelling at the MenQuadfi injection site were reported more frequently in children 2 through 9 years of age (very common) than in the older age groups.

In toddlers 12 through 23 months of age, injection site erythema and swelling (very common) at the MenQuadfi injection site, vomiting (common) and diarrhoea (common), were reported more frequently than in the older age groups. The following additional reactions, as listed below in Table 2, have been reported very commonly or commonly following administration of MenQuadfi in toddlers during clinical trials:

Table 2: Tabulated summary of adverse reactions following administration of MenQuadfi from clinical trials in subjects 12 months through 23 months

MedDRA System Organ Class	Frequency	Adverse reactions
Metabolic and nutrition disorders	Very common	Appetite lost
Psychiatric disorders	Very common	Irritability
	Uncommon	Insomnia
Nervous system disorders	Very common	Drowsiness
Gastrointestinal disorders	Common	Vomiting, diarrhoea
Skin and subcutaneous tissue disorders	Uncommon	Urticaria
General disorders and administration site conditions	Very Common	Abnormal crying
		At the injection site: tenderness/pain, erythema, swelling
	Common	Fever
	Uncommon	At the injection site: pruritus, induration, bruising, rash

Older population

Overall, within 7 days after vaccination with a single dose of MenQuadfi, the same injection site and systemic adverse reactions were observed in older (≥56 years of age) and younger adults

(18 through 55 years old) but at lower frequencies; except for injection site pruritus, which was more frequent (common) in older adults. These adverse reactions mostly were mild or moderate in intensity.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to

- the Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Overdose with MenQuadfi is unlikely due to its presentation as a single dose vial. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

Category and class: A 30.2 Antigens

Pharmacotherapeutic group: meningococcal vaccines

ATC code: J07AH08

5.1 Pharmacodynamic properties

Mechanism of action

Anti-capsular meningococcal antibodies protect against meningococcal diseases via complement mediated bactericidal activity.

MenQuadfi induces the production of bactericidal antibodies specific to the capsular polysaccharides of *Neisseria meningitidis* serogroups A, C, W, and Y.

Immunogenicity

The immunogenicity of a single dose of MenQuadfi for primary vaccination in toddlers (12 – 23 months of age), children and adolescents (2 – 17 years of age), adults (18 – 55 years of age) and older adults (56 years and above) was assessed in six pivotal studies and in one additional study in toddlers (12 – 23 months of age). The immunogenicity of a single dose of MenQuadfi for booster vaccination (subjects 15 – 55 years of age) was assessed in one pivotal study. In addition, antibody persistence after primary vaccination and immunogenicity of a booster dose was assessed in three studies in children (4 – 5 years of age), adolescents and adults (13 – 26 years of age), and older adults (≥ 59 years of age).

Primary immunogenicity analyses were conducted by measuring serum bactericidal activity (SBA) using human serum as the source of exogenous complement (hSBA). Rabbit complement (rSBA) data are available in subsets in all age groups and generally follows the trends observed with human complement (hSBA) data. In addition, all subjects were assessed for primary immunogenicity measured by hSBA and rSBA for serogroup C in MEQ00065 study.

Clinical data on the persistence of antibody response ≥ 3 years after primary vaccination with MenQuadfi in children (4 – 5 years of age), adolescents and adults (13 – 26 years of age), and older adults (≥ 59 years of age) are available. Clinical data on booster vaccination with MenQuadfi in those subjects are also available.

Immunogenicity in toddlers 12 to 23 month of age

Immunogenicity in subjects 12 through 23 months of age was evaluated in three clinical studies (MET51, MET57 and MEQ00065).

MET51 was conducted in subjects who were either meningococcal vaccine naïve or had been primed with monovalent meningococcal C conjugate vaccines in their first year of life.

Response in subjects previously vaccinated with MenC conjugate vaccines in their first year of life:

The majority of monovalent meningococcal C conjugate vaccine primed toddlers (12 through

23 months of age) in study MET51 had hSBA titres ≥ 1:8 in the MenQuadfi group (N=198) (≥ 86,7 %) and in MenACWY-TT group (N=99) (≥ 85,7 %) at D30 post-vaccination. These toddlers received during their infancy MenC-TT or MenC-CRM vaccines. Post-vaccination seroprotection rates were comparable between MenQuadfi and MenACWY-TT for all serogroups regardless of the priming background.

In MenC-CRM primed subjects the GMTs for serogroup A were lower in the MenQuadfi group (n=49) than in the MenACWY-TT group (n=25) [12,0 (8,23; 17,5) vs 42,2 (25,9; 68,8)]. After administration of MenQuadfi seroprotection rates (hSBA titres ≥ 1:8) for subjects primed with MenC- CRM were lower but still comparable for serogroups A and W compared with those in the MenACWY-TT group [A: 68 % (53,7; 81,3) vs 96,0 % (79,6; 99,9)]; W: 68,1 % (52,9; 80,9) vs 79,2 % (57,8; 92,9)]. The rates for serogroup Y were higher but still comparable with those in the MenACWY-TT group [95,8 % (85,7; 99,5) vs 80,0 % (59,3; 93,2)]. The rates for serogroup C were comparable in both groups [95,7 % (85,5; 99,5) vs 92,0 % (74,0; 99,0)]. The clinical relevance of these results is unknown. This aspect might/ be considered for individuals at high risk for MenA infection who received MenC-CRM vaccine in their first year of life.

MET57 was conducted in meningococcal vaccine naïve toddlers 12 through 23 months of age to assess the immunogenicity and safety of the concomitant administration of MenQuadfi with paediatric vaccines (MMR+V, DTaP-IPV-HB-Hib or PCV-13). Overall, the post-vaccination hSBA seroprotection rates in subjects who received MenQuadfi was high for all serogroups (between 88,9 % and 100 %). Seroresponse and seroprotection rates for serogroup A were comparable when MenQuadfi was co-administered with PCV-13 and alone (56,1 %, [95 % CI 48,9; 63,2] and 83,7 % [95 % CI 77,7; 88,6] vs 71,9 % [95 % CI 61,8; 80,6] and 90,6 % [95 % CI 82,9; 95,6]). There were differences in the hSBA GMTs for serogroup A when MenQuadfi was co-administered with PCV-13 (n=196) compared with MenQuadfi administered alone (n=96) (24,6 [95 % CI 20,2; 30,1] and 49,0 [95 % CI 36,8; 65,3]). The clinical relevance of these results is unknown, but this observation might be taken into consideration for individuals at high risk for MenA infection and consequently vaccinations with MenQuadfi and PCV13 might be performed separately.

MEQ00065 study was conducted in meningococcal vaccine naïve toddlers 12 through 23 months of age to assess the immunogenicity of serogroup C using hSBA and rSBA assays following administration of a single dose of MenQuadfi compared to MenACWY-TT or to MenC-TT.

Superiority of MenQuadfi was demonstrated in comparison to MenACWY-TT vaccine for the hSBA seroprotection rate and hSBA and rSBA GMTs to meningococcal serogroup C. Non-inferiority was demonstrated for the rSBA seroprotection rate to meningococcal serogroup C.

Superiority of MenQuadfi was also demonstrated in comparison to MenC-TT vaccine for the rSBA and hSBA GMTs to meningococcal serogroup C and non-inferiority was demonstrated for the rSBA and hSBA seroprotection rates to meningococcal serogroup C.

Immunogenicity in children 2 through 9 years of age

Immunogenicity in subjects 2 through 9 years of age was evaluated in study MET35 (stratified by ages 2 through 5 and 6 through 9 years) comparing seroresponses following administration of either MenQuadfi or MenACWY-CRM.

Overall, for subjects 2 through 9 years of age, immune non-inferiority, based on hSBA seroresponse, was demonstrated for MenQuadfi as compared to MenACWY-CRM for all four serogroups.

Immunogenicity in children and adolescents 10 through 17 years of age

Immunogenicity in subjects aged 10 through 17 years of age was evaluated in two studies comparing seroresponses following administration of MenQuadfi compared to either MenACWY-CRM (MET50 or MenACWY-DT (MET43).

MET50 was conducted in meningococcal vaccine naïve subjects and seroresponse was evaluated following administration with either MenQuadfi alone, MenACWY-CRM alone, MenQuadfi co-administered with Tdap and HPV or Tdap and HPV alone.

Study MET43 was performed to evaluate the immunogenicity of MenQuadfi compared to

MenACWY-DT in children, adolescents and adults (10 through 55 years of age).

Immunogenicity in adults 18 through 55 years of age

Immunogenicity in subjects from 18 through 55 years of age was evaluated in study MET43 comparing MenQuadfi to MenACWY-DT.

Immunogenicity in adults 56 years of age and older

Immunogenicity in adults ≥ 56 years of age (mean 67,1 years, range 56,0 – 97,2 years) was assessed in study MET49 comparing the immunogenicity of MenQuadfi to MenACWY polysaccharide vaccine.

Persistence of immune response and MenQuadfi booster response

Antibody persistence after primary vaccination and immunogenicity of a MenQuadfi booster dose was assessed in three studies in children (4 – 5 years of age), adolescents and adults (13 – 26 years of age), and older adults (≥ 59 years of age).

Persistence of immune response and MenQuadfi booster response in children 4 through 5 years of age

MET62 evaluated the antibody persistence of a primary dose, immunogenicity and safety of a booster dose of MenQuadfi in children 4 through 5 years of age. These children were primed with a single dose of MenQuadfi or MenACWY-TT 3 years before as part of the phase II study MET54 when they were 12 through 23 months old. The antibody persistence prior to the MenQuadfi booster dose and the booster immune response were assessed according to the vaccine (MenQuadfi or MenACWY-TT) children had received 3 years ago.

For all serogroups, hSBA GMTs were higher at D30 post-primary dose than at D0 pre-booster dose for MenQuadfi or MenACWY-TT. The pre-booster GMTs were higher than the pre-primary dose, indicative of long-term persistence of immune response.

After the booster dose, seroprotection rates were nearly 100 % for all serogroups in children primed with MenQuadfi.

Persistence of immune response and MenQuadfi booster response in adolescents and adults 13 through 26 years of age

MET59 evaluated the antibody persistence of primary dose, immunogenicity and safety of a booster dose of MenQuadfi in adolescents and adults 13 through 26 years of age who had received a single dose of MenQuadfi in study MET50 or MET43 or MenACWY-CRM in study MET50 or outside of Sanofi Pasteur trials 3 – 6 years prior. The antibody persistence prior to the MenQuadfi booster dose and the booster immune response were assessed according to the vaccine (MenQuadfi or MenACWY-CRM) subjects had received 3 – 6 years previously.

For all serogroups, hSBA GMTs were higher at D30 post-primary dose than at D0 pre-booster for MenQuadfi and MenACWY-CRM primed subjects. The pre-booster GMTs were higher than the pre-primary dose, indicative of long-term persistence of immune response.

After the booster dose, seroprotection rates were nearly 100 % for all serogroups in adolescents and adults primed with MenQuadfi.

Persistence of immune response and MenQuadfi booster response in adults 59 years of age and older

MEQ00066 evaluated the antibody persistence of primary dose, immunogenicity, and safety of a booster dose of MenQuadfi in adults ≥ 59 years of age who had received a single dose of MenQuadfi or MenACWY-PS ≥ 3 years previously in study MET49 or MET44.

3 year persistence

The antibody persistence prior to the MenQuadfi booster dose and the booster immune response were assessed according to the vaccine (MenQuadfi or MenACWY-PS) subjects had received 3 years previously in MET49.

For all serogroups, hSBA GMTs were higher at D30 post-primary dose than at D0 pre-booster dose for both MenQuadfi-primed and MenACWY-PS-primed adults. In addition, for both primed groups, the pre-booster GMTs were higher than the pre-primary dose for serogroups C, W and Y (indicative of long-term persistence of immune response for these serogroups) and were comparable for serogroup A.

6 – 7 year persistence

The antibody persistence was assessed according to the vaccine (MenQuadfi or MenACWY-PS) subjects had received 6 – 7 years previously in study MET44.

For all serogroups, hSBA GMTs were higher at D30 post-primary dose than at D0 pre-booster dose for MenQuadfi-primed adults. The pre-booster GMTs were higher than the pre-primary dose for serogroup C, W, and Y in MenQuadfi-primed adults, indicative of long-term persistence of immune response for these serogroups, and were comparable for serogroup A.

Booster response in adolescents and adults at least 15 years of age primed with other MenACWY vaccines

Study MET56 compared the immunogenicity of a booster dose of MenQuadfi with a booster dose of MenACWY-DT in subjects at least 15 years of age. These subjects were primed with a quadrivalent meningococcal conjugate vaccine (MenACWY-CRM (11,3 %) or with MenACWY-DT (86,3 %)) 4 to 10 years earlier.

At baseline, hSBA seroprotection and GMT were similar for serogroups A, C, W, and Y.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed.

5.3 Preclinical safety data

Non-clinical safety data revealed no special risks for humans based on a developmental and

reproductive toxicity study in female rabbits.

The administration of MenQuadfi to female rabbits at a full human dose showed no effects on mating performance, female fertility, no teratogenic potential, and no effect on pre- or post-natal development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

Sodium acetate

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

Solution in a Type I borosilicate clear glass vial with a 13 mm gray chlorobutyl stopper and a flip off seal.

Pack of 1 or 5 single dose (0,5 mL) vials.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The vaccine should be inspected visually for any particulate matter and/or variation of physical aspect (or discolouration) prior to administration. In the event of either being observed, discard the vaccine.

Preparation

Remove the flip off seal and using a suitable syringe and needle, withdraw 0,5 mL of solution, ensuring no air bubbles are present before injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th Floor

90 Bekker Road, Vorna Valley

Midrand 2196

8. REGISTRATION NUMBER

55/30.2/0612

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 September 2023

10. DATE OF REVISION OF THE TEXT

To be allocated