

(SII) Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)

MenFive

1. NAME OF THE MEDICINAL PRODUCT

MenFive Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) contains:
5 mg of each Meningococcal A, C, Y, W, and X polysaccharide individually conjugated to a carrier protein. The serogroup A and X polysaccharides are conjugated to purified tetanus toxoid (TT) and the serogroups C, Y, W, and X polysaccharides are conjugated to recombinant CRM197 cross-reactive material 197, a nontoxic mutant of diphtheria toxin protein.

Name of Ingredients	Quantity per dose (0.5 ml) after reconstitution
N. meningitidis group A polysaccharide conjugated to TT	5 µg
N. meningitidis group C polysaccharide conjugated to CRM197	5 µg
N. meningitidis group Y polysaccharide conjugated to CRM197	5 µg
N. meningitidis group W polysaccharide conjugated to CRM197	5 µg
N. meningitidis group X polysaccharide conjugated to TT	5 µg
Purified Tetanus toxoid	7.8 to 33.4 µg
Recombinant CRM197	11.7 to 50.1 µg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

MenFive is a freeze-dried formulated vaccine available in two presentations: 5-dose vial and single-dose vial. The freeze-dried vaccine is to be reconstituted with provided diluent (i.e. 0.9% sodium chloride) prior to the administration.

4. Clinical Use

For the preparation of **MenFive**, the 5-dose vaccine vial is reconstituted with 2.5 ml of provided diluent (i.e. 0.9% sodium chloride).

For the preparation of the **MenFive**, the single-dose vaccine vial is reconstituted with 0.5 ml of provided diluent (i.e. 0.9% sodium chloride).

Neither the vaccine nor the diluent contains any preservative.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications
MenFive is indicated for active immunization of individuals aged 9 months to 85 years against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, W, and X.

4.2 Dosage and method of administration
MenFive vaccine contains 5 mg of polysaccharide conjugate per 0.5 ml.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and special precautions for use
Hypersensitivity including anaphylaxis.

As with any vaccine, appropriate medical treatment and supervision should always be readily available. Anaphylaxis, anaphylactoid or other allergic type reactions are responsible following administration of **MenFive**.

4.5 Pregnancy and lactation
The vaccine is contraindicated in pregnancy.

4.6 Fertility, pregnancy and lactation
Neither the vaccine nor the diluent contains any preservative.

4.7 Effect on ability to drive and use machines

MenFive is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile:
The overall safety of **MenFive** is based on an analysis of data from five clinical trials (ACYW01, ACYW02, ACYW03, ACYW04 and DMD-20-024) in healthy individuals aged 9 months to 85 years.

Table 1: Overview of the clinical studies

Study Identification	Study Location	Study Design	Population (age range)	Study groups	Number of participants
ACYW01	United States	Randomized, Single Center, Three-Arm, Active-Controlled, Observer-Blind Study	Adults (18-45 years inclusive) Schedule of vaccination: 1 dose on Day 0	Adjusted MenFive Non-adjuncted MenFive MenACV01	20 20 20

ACYW02

ACYW02	Mal	Randomized, Single Center, Active-Controlled, Observer-Blind Study	Children (12-16 months inclusive) Schedule of vaccination: 2 doses on Day 0 and Day 84	Non-adjuncted MenFive Adjusted MenFive MenACV02	149 149 76
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ACYW03

ACYW03	Mal and The Gambia	Randomized, Multi-Center, Active-Controlled, Observer-Blind Study	Adults (18-29 years inclusive) Adults (30-44 years inclusive) Adults (45-59 years inclusive)	MenFive MenACV03 MenACV03	400 200 200
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ACYW04

ACYW04	India	Randomized, Multi-Center, Two-Arm, Active-Controlled, Observer-Blind Study	Adults (18-35 years inclusive) Schedule of vaccination: 1 dose on Day 0	MenFive MenACV04	1233 407
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DMD-20-024

DMD-20-024	Mal	Randomized, single site, blinded non-interventory trial	Infants aged 9 months (eligibility 9-11 months)	MenFive MenACV-TT	200 200
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MenACV01, MenACV02, MenACV03, MenACV04, MenACV-TT: Manufactured by Sanofi Pasteur Inc., USA

*The results are not significant differences in the reactivity and safety profile of the 2 formulations of **MenFive** (adjusted and non-adjusted), the data from the adjusted formulation are considered as representative with respect to the reactivity and safety profile of the non-adjusted formulation.

Demographic characteristics were generally similar among participants who received **MenFive** and those who received control vaccine.

The total number of doses of **MenFive** administered to participants from 9 months to 85 years of age is 3461 (of which 2146 were in non-adjusted formulation).

Adverse drug reactions

Adverse drug reactions (ADRs) are organized by MedDRA System Organ Class (SOC). Within each SOC, preferred terms are ordered by decreasing frequency and then by decreasing seriousness. Frequency of occurrence is defined as: very common (>10%); common (>1% to <10%); uncommon (>0.1% to <1%); rare (>0.01% to <0.1%); very rare (<0.01%); not known (cannot be estimated from available data).

Table 2: Adverse drug reactions

MedDRA SOC	Frequency	Adverse reactions
Nervous system disorders	Very common	Headache*
	Common	Irritability*
	Uncommon	Somnolence*
Gastrointestinal disorders	Common	Diarrhea
	Uncommon	Vomiting
Metabolism and nutrition disorders	Common	Anorexia
Musculoskeletal and connective tissue disorders	Common	Myalgia*, arthralgia*
General disorders and administration site conditions	Very common	Injection site pain/tenderness, Injection site swelling/induration, Pyrexia*, fatigue*
	Uncommon	Injection site erythema

*In children below 6 years of age

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