

FOR IMD, ONE CASE IS ONE TOO MANY



High Case Fatality Rate¹



1 year olds are most vulnerable²



Can be fatal within 24 hours¹



1 out of 6 patients die¹



Long term complications¹



Vaccines can help Prevent it¹

Meningococcal (Group A, C, W, Y)
Conjugate Vaccine



TARGET IMD FOR NEXT LEVEL PROTECTION^{*1-5}

^{*}Consistently demonstrated high immune response across all four serogroups with proven superiority against serogroup C



HIGHER SEROGENICITY AGAINST
SEROGROUP C VS COMPETITION^{1,2}

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LATTICE TECHNOLOGY
DESIGN³

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NO INTERFERENCE WITH OTHER
PEDIATRIC VACCINES⁴

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WELL-TOLERATED
ACROSS AGE GROUPS⁵

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References:
1 Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi). Summary of Product Characteristics. Date of Approval: March 2022.
2 Van Der Vliet D, Van der Vliet D, Smeets L, et al. Immunogenicity and safety of a Quadrivalent Meningococcal Intense Tandem Conjugate Vaccine (MenACYW-TT) vs. a licensed quadrivalent Meningococcal Intense Tandem Conjugate Vaccine. Safety and Immunogenicity of a Quadrivalent Meningococcal Intense Tandem Conjugate Vaccine: a phase III randomised study. *Epidemiol Infect.* 2023;151:1-10.
3 Khoshdel F, Srinivasan R, et al. An overview of structural features of arabinoside glycoconjugate vaccines that influence their immunogenicity. *Chem.* 2017;2385-4233-4254. doi:10.1039/c6cy01599g.
4 Dhanraj M, et al. Immunogenicity and Safety of a Quadrivalent Meningococcal Intense Tandem Conjugate Vaccine (MenACYW-TT) Administered Concurrently with Other Pediatric Vaccines in Toddlers: a Phase III randomised study. *Epidemiol Infect.* 2023;151:1-10. doi:10.1017/S0950268823000698. Last accessed April 2023.
5 Viskochil T, et al. How Vaccin Immunoflex. 2020. Jan 23;65:1306-1307. doi: 10.1089/978-1-61557-200-1/338691_Epub 2020 Apr 11. How Vaccin Immunoflex. 2020. Feb. 32233559 (ME15) Available at <https://pubmed.ncbi.nlm.nih.gov/32233559/> (accessed 31 March 2023).

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INVASIVE MENINGOCOCCAL DISEASE (IMD)



OUR
PROFILE



UR
LEGACY



OUR
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Sanofi Pasteur, Inc.
21st and 22nd Floors, One World Corporate Offices
32nd Street, Bonifacio Global City, Taguig, NCR Philippines

PROVIDES NEXT LEVEL PROTECTION WITH A SAFE, FULLY-LIQUID PRESENTATION AND A LONG SHELF-LIFE.

Provides IMD protection via a fully liquid vaccine with 1 dose starting at 1 year old, ready-to-use, needing no reconstitution.¹

Allows convenient storage and administration with a longer shelf-life of 48-months.¹

The only MenACWY vaccine in the Philippines approved by both US FDA* & EMA** and recommended by the ACIP***.²⁻⁶



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*Food and Drug Administration (FDA)
**European Medicines Agency (EMA)
***Advisory Committee on Immunization Practices (ACIP)

References:
1. Meningococcal Group A/C/W/Y Conjugate Vaccine (MenQuadfi). Summary of Product Characteristics. Date of approval: March 2022.
2. Sanofi, Paris, France. FDA Approval: MenQuadfi™, the latest innovation in meningococcal (MenACWY) vaccination. Retrieved from <https://www.sanofi.com/fr/fr/meds-rsvn/jems-revmsv/2022/03-04-24-05-00-00-202485>. Accessed November 2022.
3. Sanofi, Paris, France. European Commission approves MenQuadfi, the latest innovation in meningococcal (MenACWY) vaccination. Retrieved from <https://www.sanofi.com/fr/fr/meds-rsvn/jems-revmsv/2022/10/20/22-10-00-00-203477>. Accessed November 2022.
4. US FDA Approval for Meningococcal (Groups A, C, Y, W) Conjugate Vaccine (MenQuadfi). Retrieved from <https://www.fda.gov/vaccines-blood-biologics/menquadfi>. Accessed December 2022.
5. EMA Approval for Meningococcal (Groups A, C, Y, W) Conjugate Vaccine (MenQuadfi). Retrieved from <https://www.ema.europa.eu/en/medicines/humans/ETW/menquadfi>. Accessed December 2022.
6. Meningococcal Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. Centers for Disease Control and Prevention. Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/6011a1.htm>. Accessed December 2022.

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INVASIVE MENINGOCOCCAL DISEASE (IMD)



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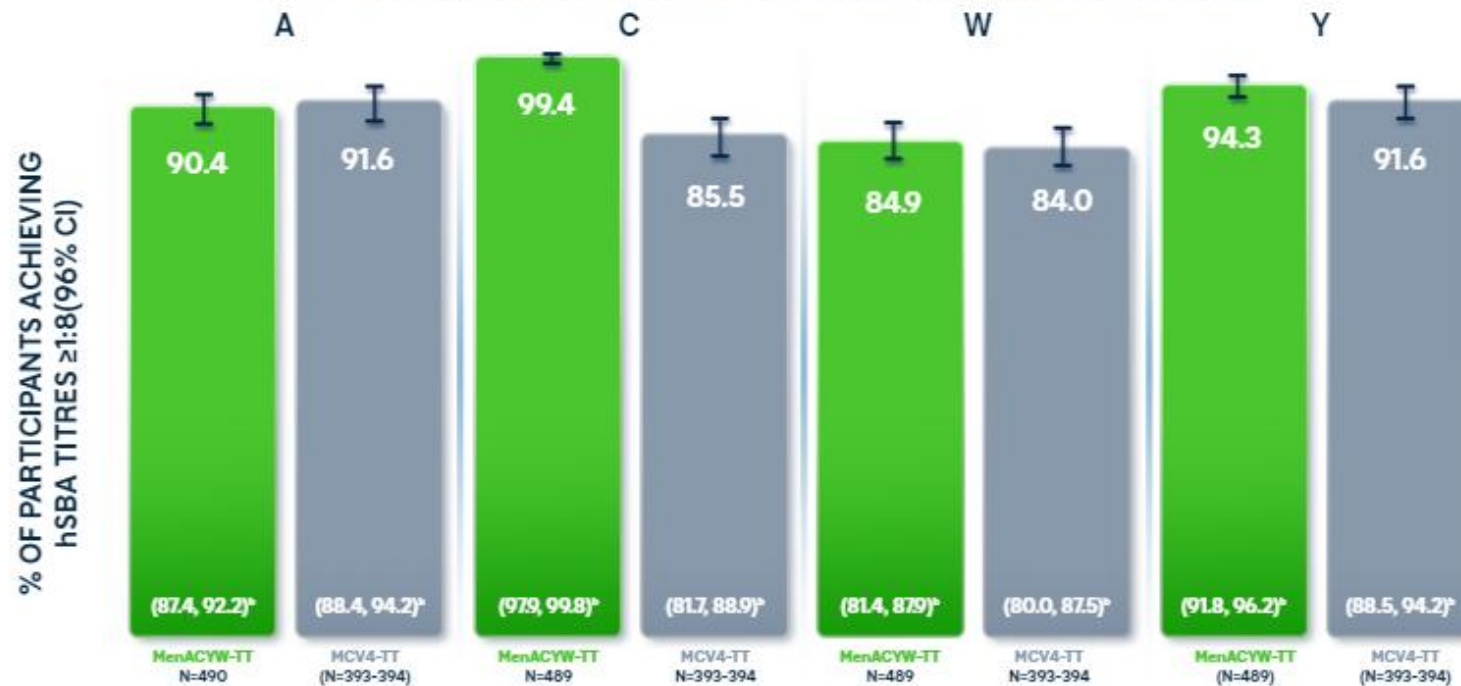
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Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) consistently demonstrated high immune response across all four serogroups.¹⁻²

HIGH SEROPROTECTION RATES vs. COMPETITION (12 to 23 months)¹



CI = confidence interval; hSBA = serum bactericidal assay using human complement; MenC = meningococcal C; N = number of participants in the per-protocol analysis set with valid serology results.

STUDY OVERVIEW

References:

1. Meningococcal Group ACWY Conjugate Vaccine (MenQuadfi). Summary of Product Characteristics. Date of approval: March 2022.
2. Van Die West D, Van der L, Sanders E, et al. Immunogenicity and safety of a quadrivalent meningococcal tetanus toxoid conjugate vaccine (MenACWY-TT) vs. a licensed quadrivalent meningococcal tetanus toxoid conjugate vaccine in meningococcal vaccine-naïve and meningococcal C conjugate vaccine-priored toddlers: a phase II randomized study. *Epidemiol Infect.* 2023;151:50. Accessed November 2023.

Immunogenicity and Safety in Toddlers 12 to 23 Months of Age



Study Population	Meningococcal Vaccine naïve and MenC primed	
Study Design	Phase III, randomized, modified double-blind study conducted across 34 sites in Germany, Finland,	
	Group 1: MenACYW-TT, naïve subject Group 2: MC4-TT naïve subjects	Group 3: MenACYW-TT, MenC primed subject Group 4: MC4-TT, MenC primed subject
Vaccination Schedule	Single dose of either vaccine	
Comparator Vaccine(s)	MCV4-TT	
Concomitant Vaccine(s)	NA	
Outcome	<p>Immunogenicity Non inferiority vs comparator in all serogroup has been demonstrated in toddlers (12-23 months) both, vaccine-naïve participants, and pooled population of participants (either vaccine-naïve or MCC-primed) at Day 30 Vaccine-naïve participants: hSBA GMTs at Day 30 for serogroups C and W were higher with non-overlapping 95% CIs in MenACYW-TT than in the MCV4-TT group, while GMTs for serogroups A and Y were comparable</p>	
	<p>Safety The most common solicited injection-site reactions were injection-site tenderness and injection-site erythema. The most common solicited systemic directions were irritability, abnormal crying, and appetite loss. Over all safety profile of MenACWY-TT and MCV4-TT were comparable and both products were generally well tolerated</p>	

References: Van Der Vliet D, Venkari T, Sandher B, et al. Immunogenicity and safety of a quadrivalent meningococcal tetanus toxoid-conjugate vaccine (MenACYW-TT) vs. a licensed quadrivalent meningococcal tetanus toxoid conjugate vaccine in meningococcal vaccine-naïve and meningococcal C conjugate vaccine-primed toddlers: a phase III randomized study. *Epidemiol Infect.* 2021;149:e50. Accessed November 2023.

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) demonstrated superior immune response against Serogroup C versus comparator vaccine.¹⁻²

hSBA seroprotection rates ($\geq 1:8$) and hSBA GMTs of serogroup C at D30 following a single dose of MenACYW-TT vs MCV4-TT[®] - hSBA PPAS



1. Non inferiority demonstrated if the lower limit of the two-sided 97.5% confidence interval (CI) of the difference in seroprotection rates was $> -10\%$
 2. Superiority demonstrated if the lower limit of the two-sided 97.5% CI of the difference in seroprotection rates was greater than 0%
 3. Non inferiority demonstrated if the lower limit of the two-sided 97.5% CI of the ratio of GMTs was $> 1/1.5$
 4. Superiority demonstrated if the lower limit of the two-sided 97.5% CI of the ratio of GMTs was > 1
- N: Number of subjects with available data at time point

Reference: Markus Knuf, Mika Rämelt, Nina Brönnholtz Starke, Isabelle Bertrand-Gerentes, Yael Thillot, Siham B'Chir, Habiba Arroum & Philipp Oster (2022). Comparing the meningococcal serogroup C immune response elicited by a tetanus toxoid conjugate quadrivalent meningococcal vaccine (MenACYW-TT) versus a quadrivalent or monovalent C tetanus toxoid conjugate meningococcal vaccine in healthy meningococcal vaccine-naïve toddlers: A randomised, controlled trial, Human Vaccines & Immunotherapeutics, DOI:10.1080/21645515.2022.205265

STUDY OVERVIEW

DATA

References:
 1 Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi). Summary of Product Characteristics. Date of approval: March 2022.
 2 Van Dine, W, D. Van der, L, Sander, K, et al. Immunogenicity and safety of a quadrivalent meningococcal tetanus toxoid conjugate vaccine (MenACYW-TT) in a licensed quadrivalent meningococcal tetanus toxoid conjugate vaccine to meningococcal vaccine-naïve and meningococcal C conjugate vaccine-naïve toddlers: a phase II randomised study. Epidemiol Infect. 2023;151:450. Accessed November 2023.
 3 Markus Knuf, Mika Rämelt, Nina Brönnholtz Starke, Isabelle Bertrand-Gerentes, Yael Thillot, Siham B'Chir, Habiba Arroum & Philipp Oster (2022). Comparing the meningococcal serogroup C immune response elicited by a tetanus toxoid conjugate quadrivalent meningococcal vaccine (MenACYW-TT) versus a quadrivalent or monovalent C tetanus toxoid conjugate meningococcal vaccine in healthy meningococcal vaccine-naïve toddlers: A randomised, controlled trial, Human Vaccines & Immunotherapeutics, DOI:10.1080/21645515.2022.205265. Accessed November 2023.

Comparing the meningococcal serogroup C immune response elicited by MenACYW-TT versus a MCV4-TT or Men C-TT in healthy toddler (12- 23 months)



Study Population	Age: 12- 23 months of age (toddler) Number of Subjects: Estimated enrolment 675 (+30 / Amendment due to COVID-19 & lockdown impact)*
Study Design	Phase III, modified double-blind, randomized (1:1:1), parallel groups, active-controlled, multi-center trial Group 1: MenACYW-TT Group 2 : MCV4-TT Group 3 : MenC-TT
Vaccination Schedule	Single dose of either vaccine
Comparator Vaccine(s)	MCV4-TT and MenC-TT
Concomitant Vaccine(s)	N/A
Outcome	Immunogenicity Superiority of MenACYW –TT was demonstrated in comparison to MCV4-TT vaccine for the hSBA seroprotection rate and hSBA and rSBA GMTs to meningococcal serogroup C. Safety The safety profile of a single dose of MenACYW-TT was comparable with MCV4-TT and Men C-TT

Reference:

Markus Knuf, Mika Rämelt, Nina Breinholt Stærke, Isabelle Bertrand-Gerentes, Yael Thollot, Siham B'Chir, Habiba Arroum & Philipp Oster (2022): Comparing the meningococcal serogroup C immune response elicited by a tetanus toxoid conjugate quadrivalent meningococcal vaccine (MenACYW-TT) versus a quadrivalent or monovalent C tetanus toxoid conjugate meningococcal vaccine in healthy meningococcal vaccine-naïve toddlers: A randomised, controlled trial, Human Vaccines & Immunotherapeutics, DOI:10.1080/21645515.2022.205265. Accessed November 2023.

Comparison of hSBA seroprotection rates ($\geq 1:8$) and hSBA GMTs for serogroup C following a single dose of MenACYW-TT vs MCV4-TT



	MenACYW-TT (N* = 214)		MCV4-TT (N* = 211)		MenACYW-TT vs MCV4-TT		Conclusion
Seroprotection Rate ($\geq 1:8$)	99.5%	(95%CI) (97.4;100)	89.1%	(95%CI) (8.41; 93.0)	Difference 10.43%	(97.5%CI) (5.68; 16.20)	NI: YES (1) SUP: YES (2)
GMTs	515	(95%CI) (450; 591)	31.6	(95%CI) (26.5; 37.6)	Ratio 16.3	(97.5%CI) (12.7; 21.0)	NI: YES (3) SUP: YES (4)

1. Non inferiority demonstrated if the lower limit of the two-sided 97.5% confidence interval (CI) of the difference in seroprotection rates was $> -10\%$
2. Superiority demonstrated if the lower limit of the two-sided 97.5% CI of the difference in seroprotection rates was greater than 0%
3. Non inferiority demonstrated if the lower limit of the two-sided 97.5% CI of the ratio of GMTs was $> 1/1.5$
4. Superiority demonstrated if the lower limit of the two-sided 97.5% CI of the ratio of GMTs was > 1

*N = Number of subjects with available data at time point

Reference: Markus Knuf, Mika Rämetsä, Nina Breinholt Stærke, Isabelle Bertrand-Gerentes, Yael Thollot, Siham B'Chir, Habiba Arroum & Philipp Oster (2022): Comparing the meningococcal serogroup C immune response elicited by a tetanus toxoid conjugate quadrivalent meningococcal vaccine (MenACYW-TT) versus a quadrivalent or monovalent C tetanus toxoid conjugate meningococcal vaccine in healthy meningococcal vaccine-naïve toddlers: A randomised, controlled trial, *Human Vaccines & Immunotherapeutics*, DOI:10.1080/21645515.2022.205265. Accessed November 2023.

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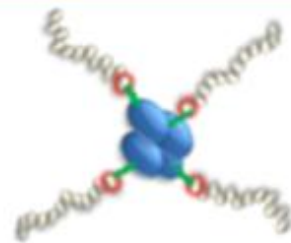
A Novel Design Made Better

MenACYW-DT

Single-point attachment

Same process chemistry per serogroup

Diphtheria toxoid protein carrier



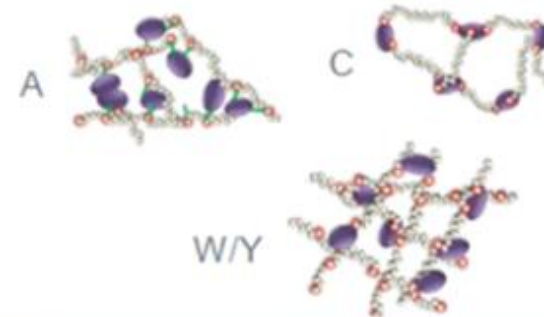
Serogroup A, C, W/Y

MenACYW-TT

Multi-point attachment

Customized process chemistry/process per serogroup maximizing yields, stability and clinical response

Tetanus toxoid protein carrier



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References:

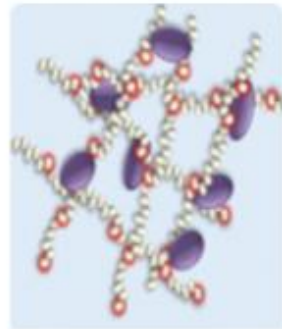
1. Koenig R et al. *Glycoconjugate J*. 2022; 44:3029-308-322
2. Meningococcal Group A, C, W, Y and W-ES Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra) SMC. Date of release: Oct 2019.
3. Meningococcal Group A, C, W, Y Conjugate Vaccine (MenQuadfi) SMC. Date of approval: March 2022



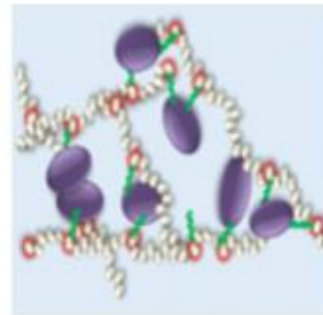
Unique Conjugation Chemistry Makes Meningococcal Group A, C, W, Y Conjugate Vaccine (MenQuadfi) Highly Immunogenic¹



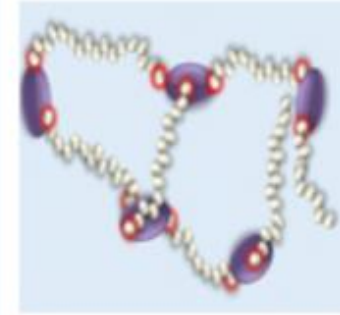
Conjugate
Chemistry



Serogroups W and Y:
Lattice conjugate



Serogroups A:
Lattice conjugate
with linker



Serogroups C:
Double point
of attachment

As a result of the chemical design of each individual serogroup, a lattice structure, which includes more than one bond for each polysaccharide, reduces the risk of releasing free polysaccharides known to negatively impact the immune response in contrast to neoglycoconjugates.¹

Lattice-type conjugates are highly immunogenic compared to neoglycoconjugates.¹

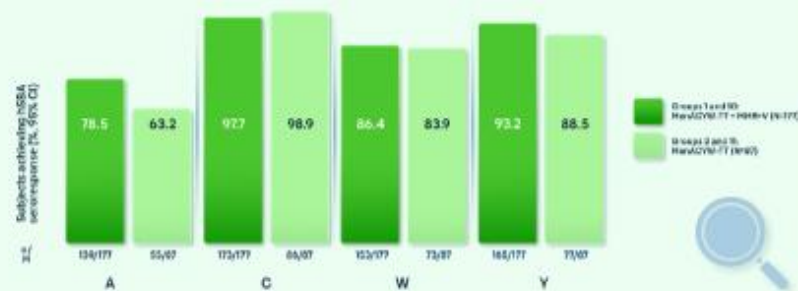
References:

1. Korstogler R et al. Glycoconjugate J. 2022 Jun;30(3):388-392
2. Meningococcal Groups A, C, W, Y and W-135 Polysaccharide Diphosphate Toxinoid Conjugate Vaccine (Menactra)
3. Meningococcal Group A, C, W, Y Conjugate Vaccine (MenQuadfi)

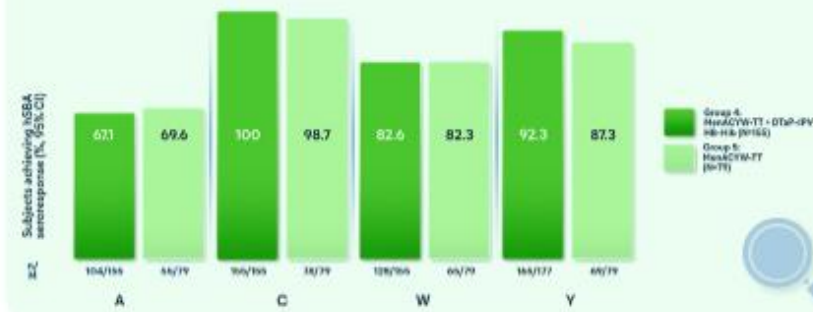


Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) can be co-administered with other pediatric vaccines with no immunologic interference

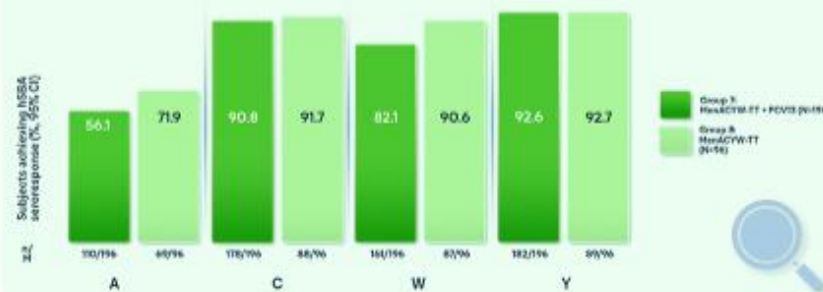
With MMRV Co Administration



With DTaP Co Administration



With PCV Co Administration



STUDY OVERVIEW

Reference:
Diazna MS et al. Immunogenicity and Safety of a Quadrivalent Meningococcal Interspersed Conjugate Vaccine (MenACWY-TT) Administered Concomitantly with Other Pediatric Vaccines to Toddlers: a Phase III randomized study. *Epidemiol Infect.* 2021;149:e90. doi:10.1017/S0950268820000698 [last accessed April 2023].
Disclaimer: This study was funded by Sanofi Pasteur.



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Comparison of groups given Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) alone vs Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) and MMRV which shows immunologic non-interference in Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi)



The hSBA vaccine seroresponse for serogroups A, C, Y and W was defined as post-vaccination hSBA titers $\geq 1:16$ for subjects with pre-vaccination titers $< 1:8$ or at least a 4-fold increase in post-vaccination hSBA titers from pre- to post-vaccination for subjects with pre-vaccination titers $\geq 1:8$. CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement. M, number of subjects with valid serology results; N, numbers of subjects in group; n, number of subjects achieving seroresponse; PPAS, per-protocol analysis set.

Comparison of groups given Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) alone vs Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) with DTaP-IPV-HB-Hib shows immunologic non-interference



The hSBA vaccine seroresponse for serogroups A, C, Y and W was defined as post-vaccination hSBA titers $\geq 1:16$ for subjects with pre-vaccination titers $< 1:8$ or at least a 4-fold increase in post-vaccination hSBA titers from pre- to post-vaccination for subjects with pre-vaccination titers $\geq 1:8$. CI, confidence interval; D30, day 30; hSBA, serum bactericidal assay using human complement. M, number of subjects with valid serology results; N, numbers of subjects in group; n, number of subjects achieving seroresponse; PPAS, per-protocol analysis set.

References:
 Reference: EU Clinical Trials Register, 2018-00472-38 (ME157) results summary August 2019. Available at: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-00472-38/results>. Accessed November 2019.

Comparison of Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi)
vs Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) plus
PCV which shows immunologic non-interference



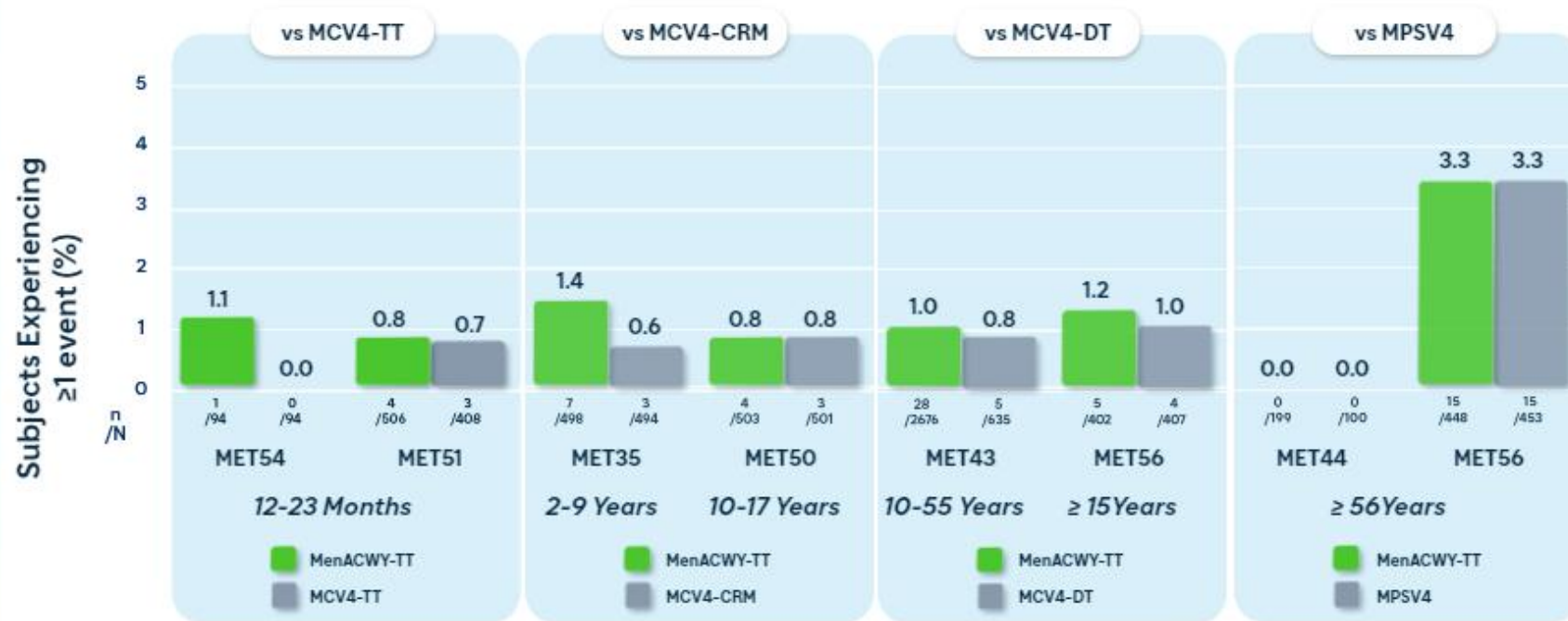
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Immunogenicity and Safety in toddlers 12 to 23 months of Age Administered contaminant with other pediatric vaccines



Study Population	Age: 12- 23 months of age (toddler) Meningococcal vaccine-naïve Number of Subjects: 1183 participants			
Study Design	Phase III, open label, randomized, active controlled study in Mexico, South Korea, Thailand, Russia			
	South Korea Group 1: MenACYW-TT + MMR+V Group 2: MenACYW-TT Group 3: MMR+V	Mexico Group 4: MenACYW-TT + DTaP-IPV-HB-Hib Group 5: MenACYW-TT Group 6: DTaP-IPV-HB-Hib	Russia Group 7: MenACYW-TT + PCV13 Group 8: MenACYW-TT Group 9: PCV13	Thailand Group 10: MenACYW-TT + MMR+V Group 11: MenACYW-TT Group 12: MMR+V
Vaccination Schedule	Single dose of either vaccine			
Comparator Vaccine(s)	MMR, Varicella (South Korea & Thailand), DTaP-IPV-HB-Hib (Mexico), PCV13 (Russia)			
Concomitant Vaccine(s)	MMR, Varicella (South Korea & Thailand), DTaP-IPV-HB-Hib (Mexico), PCV13 (Russia)			
Outcome	Immunogenicity - For both, MenACYW-TT co administered with routine pediatric vaccines and MenACYW-TT alone groups, the proportion of participants with seroprotection to each serogroup was comparable between the groups at Day 30 - The hSBA vaccine seroresponse at Day 30 was comparable for each serogroup for all participants - hSBA GMTs for each serogroup increased from baseline to Day 30 for all participants, and were comparable between the groups at Day 30 for participants from South Korea, Thailand, and Mexico			
	Safety The safety profiles of MenACYW-TT alone or in combination with MMR+V, DTaP-IPV-HepB-Hib, or PCV13 were generally comparable.			

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) is well-tolerated across different age groups across several studies and different age groups when compared to different meningococcal vaccines¹⁻⁸



SARs, serious adverse events; n, number of subjects experiencing event(s); N, number of subjects in the safety analysis set; SARs, safety analysis set; Y, years

References:
 1. Vestergaard T, et al. *Hum Vaccines Immunother*. 2020; 16(4):1016-1022. doi: 10.1080/21645515.2020.1738692. Epub 2020 Apr 15. Uman Vaccine Immunization. 2020. PMID: 32229599 (MET54) Available at <https://pubmed.ncbi.nlm.nih.gov/32229599/> [accessed 31 March 2023].
 2. Van Der West D, et al. *Epidemiol Infect*. 2020; 148(1):1-11. doi:10.1017/S0950268820000081. PMID: 32549657 (MET50) Available at <https://pubmed.ncbi.nlm.nih.gov/32549657/> [accessed 31 March 2023].
 3. Baccarini C, et al. *Public Health Dis*. 2020; 17(1):1-11. doi:10.1093/ptj/ptz000. PMID: 32549657 (MET50) Available at <https://pubmed.ncbi.nlm.nih.gov/32549657/> [accessed 31 March 2023].
 4. Cheng L, et al. *Vaccine*. 2020; 38(18):3560-3569. doi:10.1016/j.vaccine.2020.03.027. Epub 2020 Mar 20. Uman Vaccine Immunization. 2020. PMID: 32202248 (MET50) Available at <https://pubmed.ncbi.nlm.nih.gov/32202248/> [accessed 31 March 2023].

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5. Shiga M, et al. *Vaccine*. 2020; 38(18):3560-3569. doi:10.1016/j.vaccine.2020.03.027. Epub 2020 Mar 20. Uman Vaccine Immunization. 2020. PMID: 32202248 (MET50) Available at <https://pubmed.ncbi.nlm.nih.gov/32202248/> [accessed 31 March 2023].
 6. Aze G, et al. *Hum Vaccines Immunother*. 2020; 16(4):1016-1022. doi:10.1080/21645515.2020.1738692. Epub 2020 Apr 15. Uman Vaccine Immunization. 2020. PMID: 32229599 (MET54) Available at <https://pubmed.ncbi.nlm.nih.gov/32229599/> [accessed 31 March 2023].
 7. Baccarini C, et al. *Public Health Dis*. 2020; 17(1):1-11. doi:10.1093/ptj/ptz000. PMID: 32549657 (MET50) Available at <https://pubmed.ncbi.nlm.nih.gov/32549657/> [accessed 31 March 2023].
 8. Cheng L, et al. *Vaccine*. 2020; 38(18):3560-3569. doi:10.1016/j.vaccine.2020.03.027. Epub 2020 Mar 20. Uman Vaccine Immunization. 2020. PMID: 32202248 (MET50) Available at <https://pubmed.ncbi.nlm.nih.gov/32202248/> [accessed 31 March 2023].

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Sanofi is committed to the fight against Meningococcal Disease

SANOFI'S COMMITMENT TO SUSTAIN INNOVATION AGAINST MENINGOCOCCAL DISEASE^{1-5,A}

1974

First monovalent (A) meningococcal vaccine introduced^{5,b}

1978

First bivalent (A,C) meningococcal vaccine introduced^{2,b}

1981

First quadrivalent meningococcal polysaccharide vaccine introduced^{2,b}

Meningococcal Polysaccharide Vaccine Groups B, C, Y and W-135 Combined
MENOMUNE
MNCN78P-135

2005

First quadrivalent meningococcal conjugate vaccine available in liquid formulation^{3,c}

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

Menactra

2014

Following initial approval in 2005, MenACWY^d vaccine licensed for second dose^{4,c}

2020

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi) is Sanofi's latest innovation in MenACWY vaccination, designed to help protect a broad age range against invasive meningococcal disease¹

Meningococcal (Group A, C, W, Y) Conjugate Vaccine

MenQuadfi

SANOFI partners with public health stakeholders to help improve immunisation rates and access to vaccines, with a heritage of innovation and partnership that will continue into the future.

Footnote:
a. Not all products registered in all markets.
b. Discontinued.
c. Menactra[®] not approved in the EU.
d. MenACWY - Quadrivalent (serogroups A, C, W, and Y) meningococcal conjugate vaccine.

References:
1. Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi), Summary of Product Characteristics, Date of approval: March 2022.
2. Immunization Action Coalition (IAC), Accessed March 4, 2023. Vaccine Timeline. Retrieved from <https://www.imzaction.org/timeline>.
3. MenQuadfi (Prescribing Information), Sanofi Pasteur, Inc. Accessed March 4, 2023.
4. Small Pox Release, (FDA Approves Use of Meningococcal Vaccine for Biotech Immunization Against Potentially Deadly Disease. Retrieved from <https://www.fda.gov/oc/2014/03/2014032002> Accessed November 2022.
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Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) Solution for Injection

WHAT MENINGOCOCCAL GROUP A,C,W,Y CONJUGATE VACCINE (MENQUADF®) IS AND WHAT IT IS USED FOR

What Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) is used for

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) is a vaccine that can be given to children from 1 year of age, adolescents and adults. Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) helps to protect against infections caused by a type of bacteria (germs) called "Neisseria meningitidis", specifically against types A, C, W and Y. Neisseria meningitidis bacteria (also called meningococci) can be passed from person to person and can cause serious and sometimes life-threatening infections, such as:

- Meningitis – an inflammation of the tissues that surround the brain and spinal cord;

- Septicaemia – an infection of the blood.

Both infections can result in serious disease with long lasting effects or possibly death. Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) should be used in accordance with official national guidelines.

How the vaccine works

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) works by stimulating the vaccinated person natural defense (immune system), to produce protective antibodies against the bacteria. Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) only helps to protect against illnesses caused by Neisseria meningitidis types A, C, W and Y.

- It does not protect against infections caused by other types of Neisseria meningitidis.

- It does not protect against meningitis or septicaemia caused by other bacteria or viruses.

As with any vaccine, Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) may not fully protect all the people who are vaccinated.

WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN MENINGOCOCCAL GROUP A,C,W,Y CONJUGATE VACCINE (MENQUADF®)

Do not have Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) if you or your child

- are allergic to any of the active substances or any of the other ingredients of this vaccine (listed in section 6) or have experienced a previous allergic reaction to this vaccine.

If you are not sure, talk to your doctor, pharmacist or nurse before you or your child are given Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before vaccination with Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) if you or your child have:

- an infection with high temperature (over 38°C). If this applies, the vaccination will be given after the infection is under control. There is no need to delay vaccination for a minor infection such as a cold. However, talk to your doctor, pharmacist or nurse first.

- a bleeding problem or bruise easily.

- ever fainted from an injection. Fainting, sometimes accompanied by falling, can occur (mostly in adolescents) after, or even before, any injection.

- a weak immune system (such as due to HIV infection, other disease, or use of a medicine that affect the immune system), as you or your child may not fully benefit from having Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®).

If any of the above apply to you or your child (or you are not sure whether they apply), talk to your doctor, pharmacist or nurse before you or your child are given Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®). As with any vaccine, Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) may not fully protect all of those who get the vaccine.

Other medicines and Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®)

Tell your doctor, pharmacist, or nurse if you or your child are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription. In particular, tell your doctor, pharmacist, or nurse if you or your child are taking any medicines that affect your immune system, such as:

- high-dose corticosteroids
- chemotherapy.

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) may be given at the same time as other vaccines at separate injection site during the same visit.

These include the vaccines that protect against measles, mumps, rubella, varicella, diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type b, hepatitis B, pneumococcal and human papillomavirus infections.

Pregnancy and breast-feeding

If you are pregnant, breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before receiving

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®).

Driving and using machines

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) is not likely to affect your ability to drive, cycle or use machines. However, do not drive, cycle or use any machines if you are not feeling well.

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, this means that it is essentially 'sodium-free'.

HOW MENINGOCOCCAL GROUP A,C,W,Y CONJUGATE VACCINE (MENQUADF®) IS GIVEN

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) is given by a doctor or nurse as a 0.5 mL injection in the muscle. It is given in the upper arm or in the thigh depending on the age and how much muscle you or your child have.

POSSIBLE SIDE EFFECTS

Like all vaccines, Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) can cause side effects, although not everybody gets them.

If you or your child get any of these symptoms after the vaccination:

- itchy skin rash
- shortness of breath
- swelling of the face or tongue.

Contact your doctor immediately. This could be signs of an allergic reaction.

Possible side effects in children aged 12 to 23 months:

Very common (may affect more than 1 in 10 children)

- tenderness, redness, or swelling where the injection was given
- feeling irritable
- crying
- loss of appetite
- feeling drowsy

Common (may affect up to 1 in 10 children)

- fever
- vomiting
- diarrhoea

Uncommon (may affect up to 1 in 100 people):

- difficulty sleeping
- hives
- itching, bruising, firmness, or rash where the injection was given

Possible side effects in children (2 years of age and older), adolescents and adults:

Very common (may affect more than 1 in 10 people)

- pain where the injection was given
- muscle pain
- headache
- generally feeling unwell

Common (may affect up to 1 in 10 people)

- redness or swelling where the injection was given
- fever

Uncommon (may affect up to 1 in 100 people)

- itching, warmth, bruising or rash where the injection was given
- vomiting
- feeling dizzy
- nausea
- fatigue (feeling tired)

Rare (may affect up to 1 in 1,000 people)

- enlarged lymph nodes
- diarrhoea, stomach pain
- hives, itching, rash
- pain in the arms or legs
- chills, pain in the armpit
- injection site firmness

Reporting of side effects

If you or your child get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

HOW TO STORE MENINGOCOCCAL GROUP A,C,W,Y CONJUGATE VACCINE (MENQUADF®)

Keep this vaccine out of the sight and reach of children. Do not use this vaccine after the expiry date which is stated on the carton after EXP. Store in a refrigerator (2°C to 8°C). Do not freeze. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

CONTENTS OF THE PACK AND OTHER INFORMATION

What Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) contains

One dose (0.5 mL) contains:

polysaccharide1 10 micrograms, Neisseria meningitidis group C polysaccharide1 10 micrograms, Neisseria meningitidis group Y polysaccharide1 10 micrograms, Neisseria meningitidis group W polysaccharide1 10 micrograms. 1 Conjugated to tetanus toxoid carrier protein 55 micrograms.

- The other ingredients are: sodium chloride, sodium acetate, water for injections.

What Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) looks like and contents of the pack

Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) is a clear colourless solution for injection. Meningococcal Group A,C,W,Y Conjugate Vaccine (MenQuadfi®) is available in packs of 1 or 5 single dose (0.5 mL) vials. Not all pack sizes may be marketed.

Manufactured by: Sanofi Pasteur Inc., Swiftwater, PA 18370 USA This was last revised in 02/2021.

Caution Statement:

Foods, Drugs, Cosmetics Act Prohibits dispensing without prescription.