



Myocarditis Post-Marketing Reporting Rates for Nuvaxovid™

EMA Workshop on Myocarditis Post COVID-19 Vaccination
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Myocarditis reporting rates after Nuvaxovid™ vaccination by different risk windows

	0-7 Days	0-28 Days	0-42 Days	Any Report*
# of confirmed myocarditis	7	8	8	15
# of doses administered	1,569,856	1,569,856	1,569,856	1,569,856
Rate per million doses	4.5	5.1	5.1	9.6

Novavax global safety database (cases identified via broad search strategy). Data are updated through SSR12 (DLP 31DEC22)

Note: Confirmed cases only (Brighton Collaboration case definition level 1-2)

*Includes those with missing time to onset after vaccinations (TTO)

Confirmed myocarditis cases show no clustering by age group after Nuvaxovid™ vaccination

Confirmed Cases (Brighton levels 1-2) with known age and time-to-onset (any time)

Age Groups	Myocarditis/Pericarditis		Myocarditis Alone ⁺		Pericarditis Alone ⁺	
	n	%	n	%	n	%
0-19*	2	8.7%	2	18.2%	2	14.3%
20-29	3	13.0%	1	9.1%	2	14.3%
30-39	7	30.4%	4	36.4%	3	21.4%
40-49	5	21.7%	0	0%	5	35.7%
50-59	5	21.7%	4	36.4%	1	7.1%
60-69	1	4.3%	0	0%	1	7.1%
70+	0	0%	0	0%	0	0%
Total	23		11		14	

Novavax global safety database (cases identified via broad search strategy). Data are updated through SSR12 (DLP 31DEC22)

*The two cases in the 0-19 age group were 18 and 19, no cases <18

⁺ Myocarditis and Pericarditis are not exclusive. Two cases reported both myocarditis and pericarditis



Confirmed myocarditis case distribution is similar by sex after Nuvaxovid™ vaccination

Confirmed Cases (levels 1-2) with known age and time-to-onset (any time)

Sex	Myocarditis/Pericarditis		Myocarditis Alone ⁺		Pericarditis Alone ⁺	
	n	%	n	%	n	%
Male	13	56.5%	6	54.5%	9	64.3%
Female	10	43.5%	5	45.5%	5	35.7%
Total	23		11		14	

Novavax global safety database (cases identified via broad search strategy). Data are updated through SSR12 (DLP 31DEC22)

⁺ Myocarditis and Pericarditis are not mutually exclusive. Two cases reported both myocarditis and pericarditis

Myocarditis and Myocarditis/Pericarditis reporting rates are highly variable by region (EU, Australia, Japan)

		Myocarditis Cases Reported	Doses Administered	Rate/M Doses
7-day risk window	Australia	3	236,540	12.7
	Europe	4	345,231	11.6
	Japan	0	275,542	0.0
Any Report*	Australia	8	236,540	33.8
	Europe	7	345,231	20.3
	Japan	0	275,542	0.0
		Myocarditis/Pericarditis Cases Reported	Doses Administered	Rate/M Doses
7-day risk window	Australia	10	236,540	42.3
	Europe	6	345,231	17.4
	Japan	0	275,542	0.0
Any Report*	Australia	18	236,540	76.1
	Europe	9	345,231	26.1
	Japan	0	275,542	0.0

Novavax global safety database (cases identified via broad search strategy). Data are updated through SSR12 (DLP 31DEC22)

Note: Confirmed cases only (Brighton Collaboration case definition level 1-2)

*Includes those with missing TTO



Limitations of pharmacovigilance data and reporting rates

- Doses administered:
 - Incomplete or lack age information from doses administered in different countries
 - The age information available is not consistent across countries and unable to assess data by age
 - The age categories available are not compatible with those reported in the literature
 - Unable to assess age-specific doses administered globally
 - Unable to analyze reporting rates by vaccine dose globally
- Cases identified:
 - Brighton Collaboration case definitions are not exactly consistent with other case definitions (e.g., CDC)
 - Ability to follow-up cases for outcome over time in certain regions may bias the reporting rate
 - The cases from pharmacovigilance of vaccine manufacturer may be different from cases identified by medical claims, and make it challenging to compare rates from pharmacovigilance to those from database studies
- Underlying populations:
 - Very limited NVX administration to individuals <18 years which is the highest risk group for myocarditis after mRNA vaccination
 - Those vaccinated early in the pandemic may differ by important health-related characteristics compared with those receiving NVX vaccination now, which could affect the rates of adverse events. It is not possible to control for these differences using PV data

Summary

- Since conditional/emergency use authorization, around 1.6 million doses of Nuvaxovid™ have been evaluated for myocarditis reporting rates in the company global summary safety reports.
- A total of number 8 confirmed myocarditis cases (Brighton level 1-2) in the 28-day period after any dose have been reported to our global safety database.
- The distribution of myocarditis cases is not clustered in a specific age group or by sex.
- The reporting rates for myocarditis vary significantly by region and mirror the differences in regional pharmacovigilance systems.
- Novavax continues to carefully monitor the safety of Nuvaxovid™.

Thank you.