Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine

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Persons Aged ≥18 Years

Local Reactions

Among all study vaccine recipients asked to complete diaries of their symptoms during the 7 days after vaccination, 84.7% reported at least one local injection site reaction. By age group, 88.7% in the younger group (aged 18 to 55 years) and 79.7% in the older group (aged >55 years) reported at least one local reaction. Pain at the injection site was the most frequent and severe solicited local reaction among vaccine recipients. After dose 1, the younger age group reported pain more frequently than the older age group (83.1% vs 71.1%); a similar pattern was observed after dose 2 (77.8% vs 66.1%). Injection site redness and swelling following either dose were reported less frequently than injection site pain. Redness and swelling were slightly more common after dose 2. No grade 4 local reactions were reported. Overall, the median onset of local reactions in the vaccine group was 0 (day of vaccination) to 2 days after either dose and lasted a median duration between 1 and 2 days. Data on local reactions were not solicited from persons aged 16-17 years. However, their reactions to vaccination are expected to be similar to those of young adults who were included. In addition, reactogenicity data from adolescents aged 12-15 years were obtained and reviewed, and were similar to those from adults aged 18-55 years. (Table 1, Table 2)

Table 1. Local reactions in persons aged 18-55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Redness[a], n (%)				
Any	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2	10 (0.5)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Swelling[a], n (%)				

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Any	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Pain at the injection site[b], n (%)				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)

[a]Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

[b]Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

Table 2. Local reactions in persons aged >55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	Placebo N=1792	Pfizer-BioNTech Vaccine N=1660	Placebo N=1646
Redness[a], n (%)				
Any	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Grade 4	0 (0.0)	0 (0)	0 (0)	0 (0)
Swelling[a], n (%)				
Any	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0)	3 (0.2)	1 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Pain at the injection site[b], n (%)				
Any	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	127 (7.7)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0)	8 (0.5)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)

[a] Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

[b] Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

Systemic Reactions

Among all vaccine recipients asked to complete diaries of their symptoms during the 7 days after vaccination, 77.4% reported at least one systemic reaction. The frequency of systemic adverse events was higher in the younger than the older age group (82.8% vs 70.6%). Within each age group, the frequency and severity of systemic adverse events was higher after dose 2 than dose 1. Vomiting and diarrhea were exceptions, and similar between vaccine and placebo groups and regardless of dose. For both age groups, fatigue, headache and new or worsened muscle pain were most common. The majority of systemic events were mild or moderate in severity, after both doses and in both age groups. Fever was more common after the second dose and in the younger group (15.8%) compared to the older group (10.9%). Overall, the median onset of systemic adverse events in the vaccine group in general was 1 to 2 days after either dose and lasted a median duration of 1 day. Four grade 4 fevers (>40.0°C) were reported, two in the vaccine group and two in the placebo group. No other systemic grade 4 reactions were reported. Data on systemic reactions were not solicited from persons aged 16-17 years. However, their reactions to vaccination are expected to be similar to those of young adults who were included. In addition, reactogenicity data from adolescents aged 12-15 years were obtained and reviewed, and were similar to those from adults aged 18-55 years. (Table 3, Table 4)

Table 3. Systemic reactions in persons aged 18-55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Fever, n (%)				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0)	2 (0.1)	1 (0)	0 (0)
Fatigue[a], n (%)				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Headache[a], n (%)				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321)15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Chills[a], n (%)				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting[b], n (%)				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0)	1 (0)	4 (0.2)	0 (0)

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhea[c], n (%)				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0)	4 (0.2)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening muscle pain[a], n (%)				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening joint pain[a], n (%)				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0)	20 (1.0)	4 (0.2)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Use of antipyretic or pain medication	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.

[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

[c]Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.

Table 4. Systemic reactions in persons aged >55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	Placebo N=1792	Pfizer-BioNTech Vaccine N=1660	Placebo N=1646
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0)	0 (0)	0 (0)
Fatigue[a], n (%)				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	Placebo N=1792	Pfizer-BioNTech Vaccine N=1660	Placebo N=1646
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Headache[a], n (%)				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Chills[a], n (%)				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0)	1 (0.1)	17 (1.0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting[b], n (%)				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0)	1 (0.1)	0 (0)
Severe	3 (0.2)	0 (0)	1 (0.1)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhea[c], n (%)				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening muscle pain[a], n (%)				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening joint pain[a], n (%)				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.

[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

[c] Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.

Unsolicited Adverse Events

Reports of lymphadenopathy were imbalanced with 58 more cases in the vaccine group (64) than the placebo group (6); lymphadenopathy is plausibly related to the vaccine. Lymphadenopathy occurred in the arm and neck region and was reported within 2 to 4 days after vaccination. The average duration of lymphadenopathy was approximately 10 days. Bell's palsy was reported by four vaccine recipients and none of the placebo recipients. The observed frequency of reported Bell's palsy in the vaccine group is consistent with the background rate in the general population, and there is no basis upon which to conclude a causal relationship.

Serious Adverse Events

Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent disability/incapacity. The proportions of participants who reported at least 1 serious adverse event were 0.6% in the vaccine group and 0.5% in the placebo group. The most common serious adverse events in the vaccine group which were numerically higher than in the placebo group were appendicitis (7 in vaccine vs 2 in placebo), acute myocardial infarction (3 vs 0), and cerebrovascular accident (3 vs 1). Cardiovascular serious adverse events were balanced between vaccine and placebo groups. Two serious adverse events were considered by U.S. Food and Drug Administration (FDA) as possibly related to vaccine: shoulder injury possibly related to vaccine administration or to the vaccine itself, and lymphadenopathy involving the axilla contralateral to the vaccine injection site. Otherwise, occurrence of severe adverse events involving system organ classes and specific preferred terms were balanced between vaccine and placebo groups.

Data source: FDA briefing document

Persons Aged 12 – 15 Years

Local Reactions

Among all study vaccine recipients aged 12–15 years, 90.9% reported at least one local injection site reaction in the 7 days after vaccination. Pain at the injection site was the most frequent and severe solicited local reaction among vaccine recipients and was slightly more common after dose 2. No grade 4 local reactions were reported. The median onset of local reactions in the vaccine group was 0 (day of vaccination) to 2 days after either dose and lasted a median duration between 1 and 3 days. (Table 5)

Table 5. Local reactions in persons aged 12-15 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1 12-15 Years		Dose 2 12-15 Years	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Redness[a], n (%)				
Any	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0
Swelling[a], n (%)				
Any	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)

	Dose 1 12-15 Years		Dose 2 12-15 Years	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Severe	0	0	0	0
Grade 4	0	0	0	0
Pain at the injection site[b], n (%)				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0	7 (0.6)	0
Grade 4	0	0	0	0

[a]Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

[b]Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

Systemic Reactions

Among all vaccine recipients, 90.7% reported at least one systemic reaction in the 7 days after vaccination. The frequency and severity of systemic adverse events was higher after dose 2 than dose 1. Vomiting and diarrhea were exceptions, and similar between vaccine and placebo groups and regardless of dose. Fatigue, headache, chills, and new or worsened muscle pain were most common. The majority of systemic events were mild or moderate in severity, after both doses. Fever was more common after the second dose than after the first dose. Overall, the median onset of systemic adverse events in the vaccine group in general was 1 to 3 days after either dose and lasted a median duration of 1 to 2 days. One grade 4 fever (>40.0°C) was reported in the vaccine group. No other systemic grade 4 reactions were reported. (Table 6)

Table 6. Systemic reactions in persons aged 12-15 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Fever, n (%)				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0	0	0
Fatigue[a], n (%)				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
Grade 4	0	0	0	0
Headache[a], n (%)				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Grade 4	0	0	0	0
Chills[a], n (%)				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0
Grade 4	0	0	0	0
Vomiting[b], n (%)				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0
Diarrhea[c], n (%)				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0	0	0	0
Grade 4	0	0	0	0
New or worsening muscle pain[a], n (%)				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0	6 (0.5)	2 (0.2)
Grade 4	0	0	0	0
New or worsening joint pain[a], n (%)				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0	4 (0.4)	0
Grade 4	0	0	0	0
Any systemic event	877 (77.8)	636 (56.4)	904 (82.4)	439 (40.7)
Use of antipyretic or pain medication, n (%)	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)

[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.

[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

[c] Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.

Unsolicited Adverse Events

Reports of lymphadenopathy were imbalanced with 6 more cases in the vaccine group (7) than the placebo group (1); lymphadenopathy is plausibly related to the vaccine. Lymphadenopathy occurred in the arm and neck region and was reported within 2 to 4 days after vaccination. Most cases of lymphadenopathy resolved in 10 days or less. No bell's palsy or

anaphylaxis was reported among vaccine recipients in this age group.

Serious Adverse Events

The proportions of participants who reported at least 1 serious adverse event were 0.4% in the vaccine group and 0.2% in the placebo group. No serious adverse events were considered by FDA as possibly related to vaccine.

Data source: FDA Decision Memo

Page last reviewed: May 14, 2021