



# Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Janssen COVID-19 Vaccine

## Local Reactions

Local reactions were reported at higher rates by vaccine recipients than placebo recipients. The frequency of any local reaction was higher in participants aged 18 to 59 years than participants aged  $\geq 60$  years (59.8% vs 35.4%). Pain at the injection site was the most frequently reported solicited local reaction among vaccine recipients (58.6% of 18-59-year-olds and 33.3%  $\geq 60$ -year-olds). Erythema and swelling were reported less frequently. No grade 4 local reactions were reported. Overall, the median onset of local reactions in the vaccine group was within two days of vaccination, with a median duration 2 days for erythema and pain and 3 days for swelling. (Table 1)

**Table 1. Local reactions in persons aged 18–59 years and persons aged  $\geq 60$  years, Janssen COVID-19 vaccine and placebo<sup>a</sup>**

	18-59 years		$\geq 60$ years	
	Janssen Vaccine N=2036	Placebo N=2049	Janssen Vaccine N=1320	Placebo N=1331
<b>Any Local, n (%)</b>				
Any	1218 (59.8)	413 (20.2)	467 (35.4)	244 (18.3)
Grade 3	18 (0.9)	4 (0.2)	5 (0.4)	2 (0.2)
<b>Pain<sup>b</sup>, n (%)</b>				
Any	1193 (58.6)	357 (17.4)	439 (33.3)	207 (15.6)
Grade 3	8 (0.4)	0 (0.0)	3 (0.2)	2 (0.2)
<b>Erythema<sup>c</sup>, n (%)</b>				
Any	184 (9.0)	89 (4.3)	61 (4.6)	42 (3.2)
Grade 3	6 (0.3)	2 (0.1)	1 (0.1)	0 (0.0)
<b>Swelling<sup>c</sup>, n (%)</b>				
Any	142 (7.0)	32 (1.6)	36 (2.7)	21 (1.6)
Grade 3	5 (0.2)	2 (0.1)	2 (0.2)	0 (0.0)

<sup>a</sup> Solicited local and systemic adverse reactions collected for participants in a safety subset (N=6,736)

<sup>b</sup> Pain – Grade 3: any use of prescription pain reliever or prevented daily activity

<sup>c</sup> Erythema and Swelling – Grade 3: >100mm

Note: No grade 4 local reactions were reported.

## Systemic Reactions

Systemic reactions were reported at higher rates by vaccine recipients than placebo recipients. The frequency of systemic reactions was higher in participants aged 18-59 years than participants  $\geq 60$  years (61.5% vs 45.3%). For both age groups, fatigue and headache were the most commonly reported systemic reactions. Fever was more common in participants 18-59 years (12.8%) compared to those  $\geq 60$  years (3.1%). The majority of systemic reactions were mild or moderate in severity. The most common grade 3 reactions were fatigue and myalgia. No grade 4 reactions were reported. Among vaccine recipients, the median onset of systemic reactions within 2 days of vaccination, with a median duration of 1-2 days. (Table 2)

**Table 2. Systemic reactions in persons aged 18–59 years and persons aged  $\geq 60$  years, Janssen COVID–19 vaccine and placebo<sup>a</sup>**

	18-59 years		$\geq 60$ years	
	Janssen Vaccine N=2036	Placebo N=2049	Janssen Vaccine N=1320	Placebo N=1331
<b>Any systemic, n (%)</b>				
Any	1252 (61.5)	745 (36.4)	598 (45.3)	440 (33.1)
Grade 3	47 (2.3)	12 (0.6)	14 (1.1)	9 (0.7)
<b>Fatigue<sup>b</sup>, n (%)</b>				
Any	891 (43.8)	451 (22.0)	392 (29.7)	277 (20.8)
Grade 3	25 (1.2)	4 (0.2)	10 (0.8)	5 (0.4)
<b>Headache<sup>b</sup>, n (%)</b>				
Any	905 (44.4)	508 (24.8)	401 (30.4)	294 (22.1)
Grade 3	18 (0.9)	5 (0.2)	5 (0.4)	4 (0.3)
<b>Myalgia<sup>b</sup>, n (%)</b>				
Any	796 (39.1)	248 (12.1)	317 (24.0)	182 (13.7)
Grade 3	29 (1.4)	1 (<0.1)	3 (0.2)	5 (0.4)
<b>Nausea<sup>c</sup>, n (%)</b>				
Any	315 (15.5)	183 (8.9)	162 (12.3)	144 (10.8)
Grade 3	3 (0.1)	3 (0.1)	3 (0.2)	3 (0.2)
<b>Fever<sup>d</sup>, n (%)</b>				

Any	261 (12.8)	14 (0.7)	41 (3.1)	6 (0.5)
Grade 3	7 (0.3)	0 (0.0)	1 (0.1)	0 (0.0)

<sup>a</sup> Solicited local and systemic adverse reactions collected for participants in a safety subset (N=6,736)

<sup>b</sup> Fatigue, Headache, Myalgia – Grade 3: use of prescription pain reliever or prevented daily activity

<sup>c</sup> Nausea – Grade 3: prevented daily activity

<sup>d</sup> Fever – Grade 3:  $\geq 39.0 - \leq 40.0^{\circ}\text{C}$  or  $\geq 102.1 - \leq 104.0^{\circ}\text{F}$

Note: No grade 4 systemic reactions were reported.

## Analgesic/Antipyretics Use

Among vaccine recipients aged 18-59 years, 26.4% reported using antipyretic or analgesic medications, compared to 6.0% of placebo recipients. Among vaccine recipients aged  $\geq 60$  years, 9.8% reported using antipyretic or analgesic medications, compared to 5.1% of placebo recipients. The reason for medication use (e.g. fever, pain) was not ascertained.

## Unsolicited Adverse Events

Overall, rates of reported unsolicited adverse events were similar in the vaccine and placebo groups (13.1% vs 12.0%). Reports of embolic and thrombotic events had a slight numerical imbalance with 0.06% of vaccine recipients and 0.05% of placebo recipients reporting such events. Risk factors for these events were present in the participants, however vaccine cannot be excluded as a contributing factor. Reports of tinnitus had a numerical imbalance with 6 events in vaccine recipients and no events in placebo recipients. Data are insufficient at this time to determine if there is a casual relationship between the vaccine and tinnitus. Angioedema demonstrated a numerical imbalance with events reported among 0.2% of vaccine recipients and 0.1% of placebo recipients. Of these, urticaria was reported in 8 vaccine recipients and 3 placebo recipients. Based on temporal and biologic plausibility, reports of urticaria are possibly related to vaccine.

## 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 or incapacity. The proportions of participants who reported at least one serious adverse event, excluding those attributed to COVID-19, were 0.4% in the vaccine group and 0.4% in the placebo group. The most common serious adverse event occurring at higher rates in the vaccine group than the placebo group was appendicitis (6 cases in vaccine group vs. 5 cases in placebo group). Three serious adverse events occurring among vaccine recipients were considered by the U.S. Food and Drug Administration (FDA) as likely related to vaccine: the one report of hypersensitivity reaction to study vaccine, one report of pain at the injection site initially evaluated for brachial neuritis, and one report of systemic reactogenicity.

Data source: [FDA briefing document](#) 

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