

Table 1: Common unsolicited adverse events and related unsolicited adverse events up to Day 56

SOC/PT	IXIARO® 0.25 mL 2 vaccinations	IXIARO® 0.5 mL 2 vaccinations	Prevnar® 2-3 vaccinations	HAVRIX® 720 1 vaccination	p-value*
	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	n (%) [95% CI]	
AGE GROUP ≥2 MONTHS TO <1 YEAR					
N	131		64		
Unsolicited AEs with an incidence of >5% in at least 1 group					
Infections and infestations	84 (64.1) [55.3, 72.3]		36 (56.3) [43.3, 68.6]		0.347
Upper respiratory tract infections	50 (38.2) [29.8, 47.1]		24 (37.5) [25.7, 50.5]		1.000
Gastroenteritis	11 (8.4) [4.3, 14.5]		1 (1.6) [0.0, 8.4]		0.108
Impetigo	7 (5.3) [2.2, 10.7]		2 (3.1) [0.4, 10.8]		0.720
General disorders and administration site conditions	19 (14.5) [9.0, 21.7]		6 (9.4) [3.5, 19.3]		0.369
Pyrexia	19 (14.5) [9.0, 21.7]		6 (9.4) [3.5, 19.3]		0.369
Related unsolicited AEs with an incidence of >1% in at least 1 group					
ALT increased	2 (1.5) [0.2, 5.4]		1 (1.6) [0.0, 8.4]		1.000
AST increased	2 (1.5) [0.2, 5.4]		1 (1.6) [0.0, 8.4]		1.000
Pyrexia	2 (1.5) [0.2, 5.4]		0 [0.0, 5.6]		1.000
Cough	2 (1.5) [0.2, 5.4]		0 [0.0, 5.6]		1.000
Hematoma	1 (0.8) [0.0, 4.2]		1 (1.6) [0.0, 8.4]		0.550
AGE GROUP ≥1 YEAR TO <3 YEARS					
N	640			213	
Unsolicited AEs with an incidence of >5% in at least 1 group					
Infections and infestations	320 (50.0) [46.1, 53.9]			98 (46.0) [39.2, 53.0]	0.343
Upper respiratory tract infection	163 (25.5) [22.1, 29.0]			50 (23.5) [18.0, 29.7]	0.585

Nasopharyngitis	44 (6.9) [5.0, 9.1]			15 (7.0) [4.0, 11.3]	1.000
Gastroenteritis	36 (5.6) [4.0, 7.7]			11 (5.2) [2.6, 9.1]	0.864
General disorders and administration site conditions	83 (13.0) [10.5, 15.8]			25 (11.7) [7.7, 16.8]	0.722
Pyrexia	72 (11.3) [8.9, 14.0]			23 (10.8) [7.0, 15.8]	0.901
<i>Related unsolicited AEs with an incidence of >1% in at least 1 group</i>					
Upper respiratory tract infection	7 (1.1) [0.4, 2.2]			3 (1.4) [0.3, 4.1]	0.717
Pyrexia	10 (1.6) [0.8, 2.9]			4 (1.9) [0.5, 4.7]	0.758
AGE GROUP ≥3 YEARS TO <12 YEARS					
N	100	300		101	
<i>Unsolicited AEs with an incidence of >5% in at least 1 group</i>					
Infections and infestations	23 (23.0) [15.2, 32.5]	65 (21.7) [17.1, 26.8]		28 (27.7) [19.3, 37.5]	0.449
Upper respiratory tract infection	8 (8.0) [3.5, 15.2]	23 (7.7) [4.9, 11.3]		7 (6.9) [2.8, 13.8]	0.972
Nasopharyngitis	8 (8.0) [3.5, 15.2]	8 (2.7) [1.2, 5.2]		3 (3.0) [0.6, 8.4]	0.064
General disorders and administration site conditions	9 (9.0) [4.2, 16.4]	17 (5.7) [3.3, 8.9]		4 (4.0) [1.1, 9.8]	0.304
Pyrexia	8 (8.0) [3.5, 15.2]	16 (5.3) [3.1, 8.5]		4 (4.0) [1.1, 9.8]	0.450
<i>Related unsolicited AEs with an incidence of >1% in at least 1 group</i>					
Pyrexia	2 (2.0) [0.2, 7.0]	2 (0.7) [0.1, 2.4]		1 (1.0) [0.0, 5.4]	0.392
AGE GROUP ≥12 YEARS TO <18 YEARS					
N		240		80	
<i>Unsolicited AEs with an incidence of >5% in at least 1 group</i>					
Upper respiratory tract infection		26 (10.8) [7.2, 15.5]		9 (11.3) [5.3, 20.3]	1.000
<i>Related unsolicited AEs with an incidence of >1% in at least 1 group</i>					
No related AE was reported by >1% of subjects.					

Abbreviations: ALT, alanine aminotransferase, AST, aspartate aminotransferase; n, number of subjects who experienced each event; N, number of subjects in the Safety Population in the indicated vaccine and age group; NC, Not calculable, insufficient observations to perform a Fisher's exact test. PT, MedDRA preferred term; SOC, MedDRA system organ class

Note 1: p-value is from a Fisher's exact test comparing the number of subjects with the event across the treatment groups.

Note 2: Percentages are based on the number of subjects in the treatment group in a given age group. The confidence interval is an exact confidence interval for a percentage.