

Table 1: Adverse reactions from Comirnaty and Comirnaty Original/Omicron BA.1 clinical trials and Comirnaty post-authorisation experience in individuals 12 years of age and older

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Very rare (< 1/10,000)	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy ^a			
Immune system disorders			Hypersensitivity reactions (e.g. rash, pruritus, urticaria ^b , angioedema ^b)			Anaphylaxis
Metabolism and nutrition disorders			Decreased appetite			
Psychiatric disorders			Insomnia			
Nervous system disorders	Headache		Dizziness ^d ; Lethargy	Acute peripheral facial paralysis ^c		Paraesthesia ^d ; Hypoaesthesia ^d
Cardiac disorders					Myocarditis ^d ; Pericarditis ^d	
Gastrointestinal disorders	Diarrhoea ^d	Nausea; Vomiting ^d				
Skin and subcutaneous tissue disorder			Hyperhidrosis; Night sweats			Erythema multiforme ^d
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity ^c			
Reproductive system and breast disorders						Heavy menstrual bleeding ^h
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia ^f ; Injection site swelling	Injection site redness	Asthenia; Malaise; Injection site pruritus			Extensive swelling of vaccinated limb ^d ; Facial swelling ^g

- A higher frequency of lymphadenopathy (2.8% vs. 0.4%) was observed in participants receiving a booster dose in Study 4 compared to participants receiving 2 doses.
- The frequency category for urticaria and angioedema was rare.
- Through the clinical trial safety follow-up period to 14 November 2020, a acute peripheral facial paralysis (or palsy) was reported by four participants in the COVID-19 mRNA Vaccine group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.