PT. PFIZER INDONESIA
Local Product Document

Generic Name: BNT162b2 Omicron XBB.1.5 mRNA Drug Substance
Trade Name: COMIRNATY® OMICRON XBB.1.5
CDS Effective Date: 26-Jan-2024
Supersedes: NA

1. NAME OF THE MEDICINAL PRODUCT

COMIRNATY OMICRON XBB.1.5 30 micrograms/dose dispersion for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMIRNATY OMICRON XBB.1.5 is highly purified single-stranded, 5'capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Each dose contains COVID-19 mRNA vaccine embedded in lipid nanoparticles.

For the full list of excipients, see Section 6.1.

Strength per dose: 30 mcg

3. PHARMACEUTICAL FORM

Table 1. Available Presentations of COMIRNATY OMICRON XBB.1.5

Strength and Age Range of Recipient	Vial Cap and Vial Label Color	Pharmaceutical Form and Dilution Requirement	Presentation (Vial Fill Volume in mL and Number of Doses per Unit)	Appearance
30 mcg per dose for individuals 12 years of age and older	Dark grey	Dispersion for injection. Do not dilute.	Multidose vial (2.25 mL) contains six 0.3 mL doses per vial	The vaccine is a white to off-white solution.
	Light grey	Dispersion for injection. Do not dilute.	Single dose vial (0.48 mL) contains one 0.3 mL dose	The vaccine is a white to off-white solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus, in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

4.2. Posology and method of administration

Posology

Individuals 12 years of age and older

COMIRNATY OMICRON XBB.1.5 30 micrograms/dose is administered intramuscularly as a single dose of 0.3 mL for individuals 12 years of age and older regardless of prior COVID-19 vaccination status (see Sections 4.4 and 5.1).

For individuals who have previously been vaccinated with a COVID-19 vaccine, COMIRNATY OMICRON XBB.1.5 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Immunocompromised aged 12 years and older

The efficacy and safety of the COMIRNATY OMICRON XBB 1.5 vaccine has not been specifically assessed in immunocompromised individuals including those receiving immunosuppressant therapy. The efficacy of COMIRNATY OMICRON XBB 1.5 may be lower in immunocompromised individuals. Additional doses may be administered to individuals who are immunocompromised in accordance with national recommendations (see Section 4.4).

Pediatric population

The safety and efficacy of COMIRNATY OMICRON XBB.1.5 in individuals under 12 years of age have not yet been established.

The safety and effectiveness of a booster dose of COMIRNATY OMICRON XBB.1.5 in individuals 16 through 17 years of age is based on safety and effectiveness data in adults at least 18 through 55 years of age.

Elderly population

No dose adjustment is required in elderly individuals ≥ 65 years of age.

Method of administration

COMIRNATY OMICRON XBB.1.5 30 micrograms/dose dispersion for injection should be administered intramuscularly (see Section 6.6). Do not dilute prior to use.

The preferred site is the deltoid muscle of the upper arm.

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see Section 4.4.

For instructions regarding thawing, handling and disposal of the vaccine, see Section 6.6.

Single dose vials

Single dose vials of COMIRNATY OMICRON XBB.1.5 contain 1 dose of 0.3 mL of vaccine.

- Withdraw a single 0.3 mL dose of COMIRNATY OMICRON XBB.1.5.
- Discard vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

Multidose vials

Multidose vials of COMIRNATY OMICRON XBB.1.5 contain 6 doses of 0.3 mL of vaccine. In order to extract 6 doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

4.4. Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

General recommendations

Hypersensitivity and anaphylaxis

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. No further dose of the vaccine should be given to those who have experienced anaphylaxis after a prior dose of COMIRNATY.

Myocarditis and pericarditis

There is an increased risk of myocarditis and pericarditis following vaccination with COMIRNATY. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males (see section 4.8). Available data indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paraesthesia, hypoaesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY OMICRON XBB.1.5 may be lower in immunocompromised individuals.

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Limitations of vaccine effectiveness

As with any vaccine, vaccination with COMIRNATY OMICRON XBB.1.5 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their vaccination.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Concomitant administration of COMIRNATY OMICRON XBB.1.5 with other vaccines has not been studied.

Do not mix COMIRNATY OMICRON XBB.1.5 with other vaccines/products in the same syringe.

4.6. Fertility, pregnancy and lactation

Pregnancy

There is limited amount of clinical study data from the use of COMIRNATY in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development (see Section 5.3). Administration of COMIRNATY OMICRON XBB.1.5 in pregnancy should be considered when the potential benefits outweigh any potential risks for the mother and fetus.

No clinical study data are available regarding the use of variant-adapted COMIRNATY OMICRON XBB.1.5 during pregnancy.

Lactation

It is unknown whether COMIRNATY OMICRON XBB.1.5 is excreted in human milk.

No clinical study data are available regarding the use of variant-adapted COMIRNATY OMICRON XBB.1.5 during breast-feeding.

Fertility

It is unknown whether COMIRNATY OMICRON XBB.1.5 has an impact on fertility. Animal studies conducted with COMIRNATY do not indicate direct or indirect harmful effects with respect to female fertility or reproductive toxicity (see Section 5.3).

4.7. Effects on ability to drive and use machines

COMIRNATY OMICRON XBB.1.5 has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under Section 4.8 "Undesirable effects" may temporarily affect the ability to drive or use machines.

4.8. Undesirable effects

Summary of safety profile

The safety of COMIRNATY OMICRON XBB.1.5 is inferred from safety data of the prior COMIRNATY vaccines.

COMIRNATY 30 mcg

Participants 16 years of age and older – after 2 doses

In Study 2, a total of 22,026 participants 16 years of age or older received at least 1 dose of the initially approved COMIRNATY vaccine and a total of 22,021 participants 16 years of age or older received placebo (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively). A total of 20,519 participants 16 years of age or older received 2 doses of COMIRNATY.

At the time of the analysis of Study 2 with a data cut-off of 13 March 2021 for the placebo-controlled blinded follow-up period up to the participants' unblinding dates, a total of 25,651 (58.2%) participants (13,031 COMIRNATY and 12,620 placebo) 16 years of age and older were followed up for ≥ 4 months after the second dose. This included a total of 15,111 (7,704 COMIRNATY and 7,407 placebo) participants 16 to 55 years of age and a total of 10,540 (5,327 COMIRNATY and 5,213 placebo) participants 56 years of age and older.

The most frequent adverse reactions in participants 16 years of age and older that received 2 doses were injection site pain (>80%), fatigue (>60%), headache (>50%), myalgia (>40%), chills (>30%), arthralgia (>20%), pyrexia and injection site swelling (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.

The safety profile in 545 participants 16 years of age and older receiving COMIRNATY, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

Adolescents 12 to 15 years of age – after 2 doses

In an analysis of long-term safety follow-up in Study 2, 2,260 adolescents [1,131 COMIRNATY; 1,129 placebo] were 12 to 15 years of age. Of these, 1,559 adolescents [786 COMIRNATY and 773 placebo] have been followed for ≥4 months after the second dose of COMIRNATY. The safety evaluation in Study 2 is ongoing.

The overall safety profile of COMIRNATY in adolescents 12 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in adolescents 12 to 15 years of age that received 2 doses were injection site pain (>90%), fatigue and headache (>70%), myalgia and chills (>40%), arthralgia and pyrexia (>20%).

Participants 12 years of age and older – after booster dose

The safety of a booster dose of COMIRNATY in participants 12 years of age and older is inferred from safety data from studies of a booster dose of COMIRNATY in participants 16 years of age and older.

A subset from Study 2 Phase 2/3 participants of 306 adults 18 to 55 years of age who completed the original COMIRNATY 2-dose course, received a booster dose of COMIRNATY approximately 6 months (range of 4.8 to 8.0 months) after receiving Dose 2. Overall, participants who received a booster dose, had a median follow-up time of 8.3 months (range 1.1 to 8.5 months) and 301 participants had been followed for ≥ 6 months after the booster dose to the cut-off date (22 November 2021).

The overall safety profile for the booster dose was similar to that seen after 2 doses. The most frequent adverse reactions in participants 18 to 55 years of age were injection site pain (>80%), fatigue (>60%), headache (>40%), myalgia (>30%), chills and arthralgia (>20%).

In Study 4, a placebo-controlled booster study, participants 16 years of age and older recruited from Study 2 received a booster dose of COMIRNATY (5,081 participants), or placebo (5,044 participants) at least 6 months after the second dose of COMIRNATY. Overall, participants who received a booster dose, had a median follow-up time of 2.8 months (range 0.3 to 7.5 months) after the booster dose in the blinded placebo-controlled follow-up period to the cut-off date (8 February 2022). Of these, 1,281 participants [895 COMIRNATY and 386 placebo] have been followed for ≥4 months after the booster dose of COMIRNATY. No new adverse reactions of COMIRNATY were identified.

Participants 12 years of age and older – after subsequent booster doses

The safety of a booster dose of COMIRNATY in participants 12 years of age and older is inferred from safety data from studies of a booster dose of COMIRNATY in participants 18 years of age and older.

A subset of 325 adults 18 to ≤55 years of age who had completed 3 doses of COMIRNATY, received a booster (fourth dose) of COMIRNATY 90 to 180 days after receiving Dose 3. Participants who received a booster (fourth dose) of COMIRNATY had a median follow-up time of 1.4 months up to a data cut-off date of 11 March 2022. The most frequent adverse reactions in these participants were injection site pain (>70%), fatigue (>60%), headache (>40%), myalgia and chills (>20%), and arthralgia (>10%).

In a subset from Study 4 (Phase 3), 305 adults > 55 years of age who had completed 3 doses of COMIRNATY, received a booster (fourth dose) of COMIRNATY (30 mcg) 5 to 12 months after receiving Dose 3. Participants who received a booster (fourth dose) of COMIRNATY (30 mcg) had a median follow-up time of at least 1.7 months up to a data cut-off date of 16 May 2022. The overall safety profile for the COMIRNATY booster (fourth dose) was similar to that seen after the COMIRNATY booster (third dose). The most frequent adverse reactions in participants > 55 years of age were injection site pain (>60%), fatigue (>40%), headache (>20%), myalgia and chills (>10%).

Booster dose following primary vaccination with another authorised COVID-19 vaccine

In 5 independent studies on the use of a COMIRNATY booster dose in individuals who had completed primary vaccination with another authorised COVID-19 vaccine (heterologous booster dose), no new safety issues were identified (see section 5.1).

Omicron-adapted COMIRNATY

Participants 12 years of age and older – after a booster dose of COMIRNATY Original/Omicron BA.4-5 (fourth dose)

In a subset from Study 5 (Phase 2/3), 107 participants 12 to 17 years of age, 313 participants 18 to 55 years of age and 306 participants 56 years of age and older who had completed 3 doses of COMIRNATY, received a booster (fourth dose) of COMIRNATY Original/Omicron BA.4-5 (15/15 micrograms) 5.4 to 16.9 months after receiving Dose 3. Participants who received a booster (fourth dose) of COMIRNATY Original/Omicron BA.4-5 had a median follow-up time of at least 1.5 months.

The overall safety profile for the COMIRNATY Original/Omicron BA.4-5 booster (fourth dose) was similar to that seen after 3 doses. The most frequent adverse reactions in participants 12 years of age and older were injection site pain (>60%), fatigue (>50%), headache (>40%), muscle pain (>20%), chills (>10%), and joint pain (>10%).

Tabulated list of adverse reactions from clinical studies of COMIRNATY and COMIRNATY Original/Omicron BA.4-5 and post-authorisation experience of COMIRNATY in individuals 12 years of age and older.

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

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).

Table 2. Adverse reactions from COMIRNATY and COMIRNATY Original/Omicron BA.4-5 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				
Immune system disorders			Hypersensitivity reactions (e.g. rash, pruritus, urticaria[a], angioedema[a])			Anaphylaxis
Metabolism and nutrition disorders			Decreased appetite			
Psychiatric disorders			Insomnia			
Nervous system disorders	Headache		Dizziness[c]; Lethargy	Acute peripheral facial paralysis[b]		Paraesthesia[c]; Hypoaesthesia[c]
Cardiac disorders					Myocarditis[c]; Pericarditis[c]	

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)
Gastrointestinal disorders	Diarrhoea[c]	Nausea; Vomiting[c]				
Skin and subcutaneous tissue disorders			Hyperhidrosis; Night sweats			Erythema multiforme[c]
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity[d]			
Reproductive system and breast disorders						Heavy menstrual bleeding[g]
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia[e]; Injection site swelling	Injection site redness	Asthenia; Malaise; Injection site pruritus			Extensive swelling of vaccinated limb[c]; Facial swelling[f]

a. The frequency category for urticaria and angioedema was rare.
b. Through the clinical trial safety follow-up period to 14 November 2020, 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.
c. Adverse reaction determined post-authorisation.
d. Refers to vaccinated arm.
e. A higher frequency of pyrexia was observed after the second dose compared to the first dose.
f. Facial swelling in vaccine recipients with a history of injection of dermatological fillers has been reported in the post-marketing phase.
g. Most cases appeared to be non-serious and temporary in nature.

Description of selected adverse reactions

Myocarditis and pericarditis

The increased risk of myocarditis after vaccination with COMIRNATY is highest in younger males (see section 4.4).

Two large European pharmacoepidemiological studies have estimated the excess risk in younger males following the second dose of COMIRNATY. One study showed that in a period of 7 days after the second dose there were about 0.265 (95% CI 0.255 - 0.275) extra cases of myocarditis in 12-29 year old males per 10**,**000 compared to unexposed persons. In another study, in a period of 28 days after the second dose there were 0.56 (95% CI 0.37 - 0.74) extra cases of myocarditis in 16-24 year old males per 10,000 compared to unexposed persons.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor lmpor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
JI. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Website: https://e-meso.pom.go.id/ADR

PT Pfizer Indonesia
Email: IDN.AEReporting@pfizer.com
Website: www.pfizersafetyreporting.com

4.9. Overdose

Participants who received 58 micrograms of COMIRNATY OMICRON XBB.1.5 in clinical trials did not report an increase in reactogenicity or adverse events.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, viral vaccines, ATC code: J07BN01

Mechanism of action

The nucleoside-modified messenger RNA in COMIRNATY OMICRON XBB.1.5 is formulated in lipid nanoparticles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The mRNA codes for membrane-anchored, full-length S with two point mutations within the central helix. Mutation of these two amino acids to proline locks S in an antigenically preferred prefusion conformation. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

Efficacy

Omicron-adapted COMIRNATY

Immunogenicity in participants 12 years of age and older – after the booster (fourth dose)

In an analysis of a subset from Study 5, 105 participants 12 to 17 years of age, 297 participants 18 to 55 years of age, and 286 participants 56 years of age and older who had previously received a 2-dose primary series and booster dose with COMIRNATY received a booster (fourth dose) of COMIRNATY Original/Omicron BA.4-5. In participants 12 to 17 years of age, 18 to 55 years of age, and 56 years of age and older, 75.2%, 71.7% and 61.5% were positive for SARS-CoV-2 at baseline, respectively.

Analyses of 50% neutralizing antibody titres (NT50) against Omicron BA.4-5 and against reference strain among participants 56 years of age and older who received a booster (fourth dose) of COMIRNATY Original/Omicron BA.4-5 in Study 5 compared to a subset of participants from Study 4 who received a booster (fourth dose) of COMIRNATY demonstrated superiority of COMIRNATY Original/Omicron BA.4-5 to COMIRNATY based on geometric mean ratio (GMR) and noninferiority based on difference in seroresponse rates with respect to anti-Omicron BA.4-5 response, and noninferiority of anti-reference strain immune response based on GMR (**Table 3**).

Analyses of NT50 against Omicron BA.4/BA.5 among participants 18 to 55 years of age compared to participants 56 years of age and older who received a booster (fourth dose) of COMIRNATY Original/Omicron BA.4-5 in Study 5 demonstrated noninferiority of anti-Omicron BA.4-5 response among participants 18 to 55 years of age compared to participants 56 years of age and older for both GMR and difference in seroresponse rates (**Table 3**).

The study also assessed the level of NT50 of the anti-Omicron BA.4-5 SARS-CoV-2 and reference strains pre-vaccination and 1 month after vaccination in participants who received a booster (fourth dose) (**Table 4**).

Table 3. SARS-CoV-2 GMTs (NT50) and difference in percentages of participants with seroresponse at 1 month after vaccination course – COMIRNATY Original/Omicron BA.4-5 from Study 5 and COMIRNATY from subset of Study 4 – participants with or without evidence of SARS-CoV-2 infection – evaluable immunogenicity population

SARS-CoV-2 GMTs (NT50) at 1 month after vaccination course								
	Study 5 COMIRNATY Original/Omicron BA.4-5				**Subset of Study 4 COMIRNATY**		**Age group comparison**	**Vaccine group comparison**
	18 through 55 years of age		**56 years of age and older**		**56 years of age and older**		**COMIRNATY Original/ Omicron BA.4-5 18 through 55 years of age/≥ 56 years of age**	**≥ 56 years of age COMIRNATY Original/ Omicron BA.4-5 /COMIRNATY**
SARS-CoV-2 neutralization assay	**n[a]**	**GMT[c] (95% CI[c])**	**n[a]**	**GMT[b] (95% CI[b])**	**n[a]**	**GMT[b] (95% CI[b])**	**GMR[c] (95% CI[c])**	**GMR[c] (95% CI[c])**
Omicron BA.4-5 - NT50 (titre)[d]	297	4,455.9 (3,851.7, 5,154.8)	284	4,158.1 (3,554.8, 4,863.8)	282	938.9 (802.3, 1,098.8)	0.98 (0.83, 1.16)[e]	2.91 (2.45, 3.44)[f]
Reference Strain – NT50 (titre)[d]	-	-	286	16,250.1 (14,499.2, 18,212.4)	289	10,415.5 (9,366.7, 11,581.8)	-	1.38 (1.22, 1.56)[g]
Difference in percentages of participants with seroresponse at 1 month after vaccination course								
	COMIRNATY Original/Omicron BA.4-5				**Subset of Study 4 COMIRNATY**		**Age group comparison**	**Vaccine group comparison ≥ 56 years of age**
	18 through 55 years of age		**56 years of age and older**		**56 years of age and older**		**COMIRNATY Original/Omicron BA.4-5 18 through 55 years of age/≥ 56**	**COMIRNATY Original/ Omicron BA.4-5 /COMIRNATY**
SARS-CoV-2 neutralization assay	**N[h]**	**n[i] (%) (95% CI[k])**	**N[h]**	**n[i] (%) (95% CI[k])**	**N[h]**	**n[i] (%) (95% CI[j])**	**Difference[k] (95% CI[l])**	**Difference[k] (95% CI[l])**
Omicron BA.4-5 - NT50 (titre)[d]	294	180 (61.2) (55.4, 66.8)	282	188 (66.7) (60.8, 72.1)	273	127 (46.5) (40.5, 52.6)	-3.03 (-9.68, 3.63)[m]	26.77 (19.59, 33.95)[n]

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titre; LLOQ = lower limit of quantitation; LS = least square; NT50 = 50% neutralizing titre; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Seroresponse is defined as achieving a ≥ 4-fold rise from baseline. If the baseline measurement is below the LLOQ, a postvaccination assay result ≥ 4 × LLOQ is considered a seroresponse.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titres and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
c. GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of LS means and corresponding CIs based on analysis of logarithmically transformed neutralizing titres using a linear regression model with terms of baseline neutralizing titre (log scale) and vaccine group or age group.
d. SARS-CoV-2 NT50 were determined using a validated 384-well assay platform (original strain [USA-WA1/2020, isolated in January 2020] and Omicron B.1.1.529 subvariant BA.4/BA.5).
e. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
f. Superiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 1.
g. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67 and the point estimate of the GMR is ≥ 0.8.
h. N = Number of participants with valid and determinate assay results for the specified assay at both the prevaccination time point and the given sampling time point. This value is the denominator for the percentage calculation.
i. n = Number of participants with seroresponse for the given assay at the given sampling time point.
j. Exact 2-sided CI, based on the Clopper and Pearson method.
k. Difference in proportions, expressed as a percentage.
l. 2-sided CI based on the Miettinen and Nurminen method stratified by baseline neutralizing titre category (< median, ≥ median) for the difference in proportions. The median of baseline neutralizing titres was calculated based on the pooled data in 2 comparator groups.
m. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the difference in percentages of participants with seroresponse is > -10%.
n. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the difference in percentages of participants with seroresponse is > -5%.

Table 4. Geometric mean titres – COMIRNATY Original/Omicron BA.4-5 subsets of Study 5 –prior to and 1 month after booster (fourth dose) – participants 12 years of age and older – with or without evidence of infection - evaluable immunogenicity population

SARS-CoV-2 neutralization assay	Sampling time point[a]	COMIRNATY Original/Omicron BA.4-5					
		12 through 17 years of age		18 through 55 years of age		56 years of age and older	
		n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
Omicron BA.4-5 - NT50 (titre)[d]	Pre-vaccination	104	1,105.8 (835.1, 1,464.3)	294	569.6 (471.4, 688.2)	284	458.2 (365.2, 574.8)
	1 month	105	8,212.8 (6,807.3, 9,908.7)	297	4,455.9 (3,851.7, 5,154.8)	284	4,158.1 (3,554.8, 4,863.8)
Reference Strain – NT50 (titre)[d]	Pre-vaccination	105	6,863.3 (5,587.8, 8,430.1)	296	4,017.3 (3,430.7, 4,704.1)	284	3,690.6 (3,082.2, 4,419.0)
	1 month	105	23,641.3 (20,473.1, 27,299.8)	296	16,323.3 (14,686.5, 18,142.6)	286	16,250.1 (14,499.2, 18,212.4)

Abbreviations: CI = confidence interval; GMT = geometric mean titre; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titre; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titres and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. SARS-CoV-2 NT50 were determined using a validated 384-well assay platform (original strain [USA-WA1/2020, isolated in January 2020] and Omicron B.1.1.529 subvariant BA.4-5).

COMIRNATY 30 mcg

Study 2 is a multicenter, multinational, Phase 1/2/3 randomised, placebo-controlled, observer-blind dose-finding, vaccine candidate selection and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 to 15 years of age, 16 to 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with HIV, hepatitis C virus (HCV), or hepatitis B virus (HBV).

Efficacy in participants 16 years of age and older – after 2 doses

In the Phase 2/3 portion of Study 2, based on data accrued through 14 November 2020, approximately 44,000 participants were randomized equally and were to receive 2 doses of the initially approved COVID-19 mRNA Vaccine or placebo. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. The majority (93.1%) of vaccine recipients received the second dose 19 days to 23 days after Dose 1. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19. In the clinical study, participants were required to observe a minimum interval of 14 days before and after administration of an influenza vaccine in order to receive either placebo or COVID-19 mRNA Vaccine. In the clinical study, participants were required to observe a minimum interval of 60 days before or after receipt of blood/plasma products or immunoglobulins within through conclusion of the study in order to receive either placebo or COVID-19 mRNA Vaccine.

The population for the analysis of the primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. In addition, 134 participants were between the ages of 16 to 17 years of age (66 in the COVID-19 mRNA Vaccine group and 68 in the placebo group) and 1,616 participants 75 years of age and older (804 in the COVID-19 mRNA Vaccine group and 812 in the placebo group).
At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for at least 2214 person-years for the COVID-19 mRNA Vaccine and in total 2222 person-years in the placebo group.

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 [e.g., asthma, body mass index (BMI) ≥30 kg/m^2, chronic pulmonary disease, diabetes mellitus, hypertension].

The vaccine efficacy information is presented in **Table 5**.

Table 5. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**COMIRNATY N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)[e]**
All participants[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)
⩾65 years	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8)
⩾75 years	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 [*Case definition: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhoea or vomiting.].

* Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time. CI not adjusted for multiplicity.

Efficacy of COVID-19 mRNA Vaccine in preventing first COVID-19 occurrence from 7 days after Dose 2 compared to placebo was 94.6% (95% confidence interval of 89.6% to 97.6%) in participants 16 years of age and older with or without evidence of prior infection with SARS-CoV-2.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.

The updated vaccine efficacy information is presented in **Table 6**.

Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Prior SARS-CoV-2 Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period

Subgroup	COMIRNATY N[a]=20,998 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=21,096 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
All participants[f]	77 6.247 (20,712)	850 6.003 (20,713)	91.3 (89.0, 93.2)
16 through 64 years	70 4.859 (15,519)	710 4.654 (15,515)	90.6 (87.9, 92.7)
65 years and older	7 1.233 (4192)	124 1.202 (4226)	94.5 (88.3, 97.8)
65 through 74 years	6 0.994 (3350)	98 0.966 (3379)	94.1 (86.6, 97.9)
75 years and older	1 0.239 (842)	26 0.237 (847)	96.2 (76.9, 99.9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided 95% confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

f. Included confirmed cases in participants 12 through 15 years of age: 0 in the COVID 19 mRNA Vaccine group; 16 in the placebo group.

In the updated efficacy analysis, efficacy of COVID-19 mRNA Vaccine in preventing first COVID-19 occurrence from 7 days after Dose 2 compared to placebo was 91.1% (95% CI of 88.8% to 93.0%) during the period when Wuhan/Wild type and Alpha variants were the predominant circulating strains in participants in the evaluable efficacy population with or without evidence of prior infection with SARS-CoV-2.

Additionally, the updated efficacy analyses by subgroup showed similar efficacy point estimates across sexes, ethnic groups, geography and participants with medical comorbidities and obesity associated with high risk of severe COVID-19.

Efficacy against severe COVID-19

Updated efficacy analyses of secondary efficacy endpoints supported benefit of the COVID-19 mRNA Vaccine in preventing severe COVID-19.

As of 13 March 2021, vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (**Table 7**) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the COVID-19 mRNA Vaccine and placebo groups.

Table 7. Vaccine Efficacy – First Severe COVID-19 Occurrence in Participants With or Without Prior SARS-CoV-2 Infection Based on the Food and Drug Administration (FDA)† After Dose 1 or From 7 Days After Dose 2 in the Placebo-Controlled Follow-up

	COVID-19 mRNA Vaccine Cases n1[a] Surveillance Time (n2[b])	Placebo Cases n1[a] Surveillance Time (n2[b])	Vaccine Efficacy % (95% CI[c])
After Dose 1[d]	1 8.439[e] (22,505)	30 8.288[e] (22,435)	96.7 (80.3, 99.9)
7 days after Dose 2[f]	1 6.522[g] (21,649)	21 6.404[g] (21,730)	95.3 (70.9, 99.9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

† Severe illness from COVID-19 as defined by FDA is confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥125 beats per minute, saturation of oxygen ≤93% on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen <300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];
- Evidence of shock (systolic blood pressure <90 mm Hg, diastolic blood pressure <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an Intensive Care Unit;
- Death.

a. n1 = Number of participants meeting the endpoint definition.
b. n2 = Number of participants at risk for the endpoint.
c. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
d. Efficacy assessed based on the Dose 1 all-available efficacy (modified intention-to-treat) population that included all randomized participants who received at least 1 dose of study intervention.
e. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.

f. Efficacy assessed based on the evaluable efficacy (7 Days) population that included all eligible randomized participants who receive all dose(s) of study intervention as randomized within the predefined window, have no other important protocol deviations as determined by the clinician.
g. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

Efficacy and immunogenicity in adolescents 12 to 15 years of age – after 2 doses

In an initial analysis of Study 2 in adolescents 12 to 15 years of age (representing a median follow-up duration of > 2 months after Dose 2) without evidence of prior infection, there were no cases in 1,005 participants who received the vaccine and 16 cases out of 978 who received placebo. The point estimate for efficacy is 100% (95% confidence interval 75.3, 100.0). In participants with or without evidence of prior infection there were 0 cases in the 1,119 who received vaccine and 18 cases in 1,110 participants who received placebo. This also indicates the point estimate for efficacy is 100% (95% confidence interval 78.1, 100.0).

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up, representing up to 6 months after Dose 2 in the efficacy population.

In the updated efficacy analysis of Study 2 in adolescents 12 to 15 years of age without evidence of prior infection, there were no cases in 1,057 participants who received the vaccine and 28 cases out of 1,030 who received placebo. The point estimate for efficacy is 100% (95% confidence interval 86.8, 100.0) during the period when Alpha variant was the predominant circulating strain. In participants with or without evidence of prior infection there were 0 cases in the 1,119 who received vaccine and 30 cases in 1,109 participants who received placebo. This also indicates the point estimate for efficacy is 100% (95% confidence interval 87.5, 100.0).

In Study 2, an analysis of SARS-CoV-2 neutralising titres 1 month after Dose 2 was conducted in a randomly selected subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2, comparing the response in adolescents 12 to 15 years of age (n = 190) to participants 16 to 25 years of age (n = 170).

The ratio of the geometric mean titres (GMT) in the 12 to 15 years of age group to the 16 to 25 years of age group was 1.76, with a 2-sided 95% CI of 1.47 to 2.10. Therefore, the 1.5-fold noninferiority criterion was met as the lower bound of the 2-sided 95% CI for the geometric mean ratio [GMR] was > 0.67.

Immunogenicity in participants 18 years of age and older – after booster dose

Effectiveness of a booster dose of COMIRNATY was based on an assessment of 50% neutralizing antibody titres (NT50) against SARS-CoV-2 (USA_WA1/2020) in Study 2. In this study, the booster dose was administered 5 to 8 months (median 7 months) after the second dose. In Study 2, analyses of NT50 1 month after the booster dose compared to 1 month after the primary series in individuals 18 through 55 years of age who had no

serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster vaccination demonstrated noninferiority for both geometric mean ratio (GMR) and difference in seroresponse rates. Seroresponse for a participant was defined as achieving a ≥ 4-fold rise in NT50 from baseline (before primary series). These analyses are summarized in **Table 8**.

Table 8. SARS-CoV-2 neutralization assay - NT50 (titre)† (SARS-CoV-2 USA_WA1/2020) – GMT and seroresponse rate comparison of 1 month after booster dose to 1 month after primary series – participants 18 through 55 years of age without evidence of infection up to 1 month after booster dose* – booster dose evaluable immunogenicity population±

	n	1 month after booster dose (95% CI)	1 month after primary series (95% CI)	1 month after booster dose - 1 month after primary series (97.5% CI)	Met noninferiority objective (Y/N)
Geometric mean 50% neutralizing titre (GMT[b])	212[a]	2,466.0[b] (2,202.6, 2,760.8)	755.7[b] (663.1, 861.2)	3.26[c] (2.76, 3.86)	Y[d]
Seroresponse rate (%) for 50% neutralizing titre†	200[e]	199[f] 99.5% (97.2%, 100.0%)	190[f] 95.0% (91.0%, 97.6%)	4.5%[g] (1.0%, 7.9%[h])	Y[i]

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titre; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titre; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

† SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

* Participants who had no serological or virological evidence (up to 1 month after receipt of a booster dose of COMIRNATY) of past SARS-CoV-2 infection (i.e. N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after the booster dose were included in the analysis.

± All eligible participants who had received 2 doses of COMIRNATY as initially randomised, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of COMIRNATY, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.

a. n = Number of participants with valid and determinate assay results at both sampling time points within specified window.

b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titres and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

c. GMRs and 2-sided 97.5% CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution).
d. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the GMR is > 0.67 and the point estimate of the GMR is ≥ 0.80.
e. n = Number of participants with valid and determinate assay results for the specified assay at baseline, 1 month after Dose 2 and 1 month after the booster dose within specified window. These values are the denominators for the percentage calculations.
f. Number of participants with seroresponse for the given assay at the given dose/sampling time point. Exact 2-sided CI based on the Clopper and Pearson method.
g. Difference in proportions, expressed as a percentage (1 month after booster dose – 1 month after Dose 2).
h. Adjusted Wald 2-sided CI for the difference in proportions, expressed as a percentage.
i. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the percentage difference is > -10%.

Relative vaccine efficacy in participants 16 years of age and older – after booster dose

An interim efficacy analysis of Study 4, a placebo-controlled booster study performed in approximately 10,000 participants 16 years of age and older who were recruited from Study 2, evaluated confirmed COVID-19 cases accrued from at least 7 days after booster vaccination up to a data cut-off date of 5 October 2021, which represents a median of 2.5 months post-booster follow-up. The booster dose was administered 5 to 13 months (median 11 months) after the second dose. Vaccine efficacy of the COMIRNATY booster dose after the primary series relative to the placebo booster group who only received the primary series dose was assessed.

The relative vaccine efficacy information for participants 16 years of age and older without prior evidence of SARS-CoV-2 infection is presented in **Table 9**. Relative vaccine efficacy in participants with or without evidence of prior SARS-CoV-2 infection was 94.6% (95% confidence interval of 88.5% to 97.9%), similar to that seen in those participants without evidence of prior infection. Primary COVID-19 cases observed from 7 days after booster vaccination were 7 primary cases in the COMIRNATY group, and 124 primary cases in the placebo group.

Table 9. Vaccine efficacy – First COVID-19 occurrence from 7 days after booster vaccination – participants 16 years of age and older without evidence of infection – evaluable efficacy population

First COVID-19 occurrence from 7 days after booster dose in participants without evidence of prior SARS-CoV-2 infection*			
	COMIRNATY N[a]=4,695 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=4,671 Cases n1[b] Surveillance Time[c] (n2[d])**	**Relative Vaccine Efficacy[e] % (95% CI[f])**
First COVID-19 occurrence from 7 days after booster vaccination	6 0.823 (4,659)	123 0.792 (4,614)	95.3 (89.5, 98.3)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhoea; vomiting).

* Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (i.e. N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Relative vaccine efficacy of the COMIRNATY booster group relative to the placebo group (non-booster).
f. Two-sided confidence interval (CI) for relative vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

Immunogenicity of a booster dose following primary vaccination with another authorised COVID-19 vaccine

Effectiveness of a COMIRNATY booster dose (30 mcg) in individuals who completed primary vaccination with another authorised COVID-19 vaccine (heterologous booster dose) is inferred from immunogenicity data from an independent National Institutes of Health (NIH) study phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States. In this study, adults (range 19 to 80 years of age) who had completed primary vaccination with Moderna 100 mcg 2-dose series (N = 51, mean age 54±17), Janssen single dose (N = 53, mean age 48±14), or COMIRNATY 30 mcg 2-dose series (N = 50, mean age 50±18) at least 12 weeks prior to enrolment and who reported no history of SARS-CoV-2 infection received a booster dose of COMIRNATY (30 mcg). The boost with COMIRNATY induced a 36, 12, and 20 GMR-fold rise in neutralising titres following the Janssen, Moderna, and COMIRNATY primary doses, respectively.

Heterologous boosting with COMIRNATY was also evaluated in the CoV-BOOST study (EudraCT 2021-002175-19), a multicentre, randomised, controlled, phase 2 trial of third dose booster vaccination against COVID-19, in which 107 adult participants

(median age 71 years of age, interquartile range 54 to 77 years of age) were randomised at least 70 days post 2 doses of AstraZeneca COVID-19 Vaccine. After the AstraZeneca COVID-19 Vaccine primary series, pseudovirus (wild-type), neutralising antibody NT50 GMR-fold change increased 21.6-fold with heterologous COMIRNATY booster (n = 95).

Immunogenicity in participants > 55 years of age – after a booster dose (fourth dose) of COMIRNATY (30 mcg)

In an interim analysis of a subset from Study 4 (Substudy E), 305 participants > 55 years of age who had completed a series of 3 doses of COMIRNATY received COMIRNATY (30 mcg) as a booster dose (fourth dose) 5 to 12 months after receiving Dose 3. For the Immunogenicity subset data see **Table 10**.

Immunogenicity in participants 18 to ≤ 55 years of age – after a booster dose (fourth dose) of COMIRNATY (30 mcg)

In Substudy D [a subset from Study 2 (Phase 3) and Study 4 (Phase 3)], 325 participants 18 to ≤ 55 years of age who had completed 3 doses of COMIRNATY received COMIRNATY (30 mcg) as a booster dose (fourth dose) 90 to 180 days after receiving Dose 3. For the Immunogenicity subset data see **Table 10**.

Table 10. Summary of immunogenicity data from participants in C4591031 Substudy D (cohort 2 full expanded set) and Substudy E (expanded cohort immunogenicity subset) who received COMIRNATY 30 mcg as booster (fourth dose) – participants without evidence of infection up to 1 month after booster dose – evaluable immunogenicity population

	Dose/ sampling time point[a]	**Substudy D (18 to ≤ 55 years of age) COMIRNATY 30 mcg**		**Substudy E (> 55 years of age) COMIRNATY 30 mcg**	
GMT		**N[b]**	**GMT (95% CI[d])**	**N[b]**	**GMT (95% CI[d])**
SARS-CoV-2 neutralization assay – Omicron BA.1 – NT50 (titre)	1/Prevax	226	315.0 (269.0, 368.9)	167	67.5 (52.9, 86.3)
	1/1 Month	228	1,063.2 (935.8, 1,207.9)	163	455.8 (365.9, 567.6)
SARS-CoV-2 neutralization assay – reference strain – NT50 (titre)	1/Prevax	226	3,999.0 (3,529.5, 4,531.0)	179	1,389.1 (1,142.1, 1,689.5)
	1/1 Month	227	12,009.9 (10,744.3, 13,424.6)	182	5,998.1 (5,223.6, 6,887.4)
Seroresponse rate at 1 month post-Dose 4		**N[c]**	**n[e] (%) (95% CI[f])**	**N[c]**	**n[e] (%) (95% CI[f])**

	Dose/ sampling time point[a]	Substudy D (18 to ≤ 55 years of age) COMIRNATY 30 mcg		Substudy E (> 55 years of age) COMIRNATY 30 mcg	
GMT		N[b]	GMT (95% CI[d])	N[b]	GMT (95% CI[d])
SARS-CoV-2 neutralization assay – Omicron BA.1 – NT50 (titre)	1/1 Month	226	91 (40.3%) (33.8, 47.0)	149	85 (57.0%) (48.7, 65.1)
SARS-CoV-2 neutralization assay – reference strain – NT50 (titre)	1/1 Month	225	76 (33.8%) (27.6, 40.4)	179	88 (49.2%) (41.6, 56.7)

Abbreviations: CI = confidence interval; GMT = geometric mean titre; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralising titre; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Median time from Dose 3 to Dose 4 of COMIRNATY 30 mcg is 4.0 months for Substudy D Cohort 2 and 6.3 months for Substudy E expanded cohort.
Note: Substudy D Full Expanded Set = Cohort 2 excluding the sentinel group; Substudy E Immunogenicity Subset = a random sample of 230 participants in each vaccine group selected from the expanded cohort.
Note: Participants who had no serological or virological evidence (prior to the 1-month post–study vaccination blood sample collection) of past SARS-CoV-2 infection (i.e. N-binding antibody [serum] result negative at the study vaccination and the 1-month post–study vaccination visits, negative NAAT [nasal swab] result at the study vaccination visit, and any unscheduled visit prior to the 1-month post–study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.
Note: Seroresponse is defined as achieving ≥ 4-fold rise from baseline (before the study vaccination). If the baseline measurement is below the LLOQ, the post-vaccination measure of ≥ 4 × LLOQ is considered a seroresponse.

a. Protocol-specified timing for blood sample collection.
b. N = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. N = Number of participants with valid and determinate assay results for the specified assay at both the pre-vaccination time point and the given sampling time point.
d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titres and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
e. n = Number of participants with seroresponse for the given assay at the given sampling time point.
f. Exact 2-sided CI, based on the Clopper and Pearson method.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.

General toxicity

Rats intramuscularly administered COMIRNATY (receiving 3 full human doses once weekly, generating relatively higher levels in rats due to body weight differences) demonstrated some injection site oedema and erythema and increases in white blood cells (including basophils and eosinophils) consistent with an inflammatory response as

well as vacuolation of portal hepatocytes without evidence of liver injury. All effects were reversible.

Genotoxicity/Carcinogenicity

Neither genotoxicity nor carcinogenicity studies were performed. The components of the vaccine (lipids and mRNA) are not expected to have genotoxic potential.

Reproductive toxicity

Reproductive and developmental toxicity were investigated in rats in a combined fertility and developmental toxicity study where female rats were intramuscularly administered COMIRNATY prior to mating and during gestation (receiving 4 full human doses that generate relatively higher levels in rat due to body weight differences, spanning between pre-mating day 21 and gestational day 20). SARS-CoV-2 neutralizing antibody responses were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in foetuses and offspring. There were no vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development. No COMIRNATY data are available on vaccine placental transfer or excretion in milk.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
Cholesterol
Tromethamine
Tromethamine hydrochloride
Sucrose
Water for injections

6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Sections 6.3 and 6.6.

6.3. Shelf life

COMIRNATY OMICRON XBB.1.5 may be received frozen at -90°C to -60°C. Frozen vaccine can be stored either at -90°C to -60°C or 2°C to 8°C upon receipt.

Thawing Frozen Vials

- Frozen (-90°C to -60°C) vials can be thawed at either 2°C to 8°C or at temperatures up to 30°C (see Section 6.6 for more detailed thawing instructions).
- Once thawed, the vaccine should not be re-frozen.

Shelf Life of Refrigerated Vials

- Frozen vials may be transferred to refrigerated storage (2°C to 8°C) upon receipt. Once moved to refrigerated storage, unopened vials may be stored for a single period of up to 10 weeks, not exceeding the original printed expiry date (EXP).
- Upon moving the product to 2°C to 8°C storage, the original expiry date on the outer carton should be crossed out and updated expiry date must be written (10 weeks from the date the vials were removed from frozen storage). The vaccine should be used or discarded by the updated expiry date.
- If the vaccine is received refrigerated (2°C to 8°C) it should be stored at 2°C to 8°C. Check that the expiry date on the outer carton has been updated to reflect the refrigerated expiry date and that the original expiry date has been crossed out.

Storage of Thawed, Opened (punctured) Vials

- Vials may be stored at temperatures between 8°C to 30°C for a total of 24 hours, inclusive of storage before and after puncture. Once a vial has been punctured chemical and physical in-use stability has been demonstrated for 12 hours at 2°C to 30°C.
- From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately after the first puncture of single dose vials and within 12 hours after puncture of multidose vials. If not used within the recommended duration, in-use storage times and conditions are the responsibility of the user.

6.4. Special precautions for storage

Store COMIRNATY OMICRON XBB.1.5 in the original package in order to protect from light.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vials can be handled in room light conditions.

For storage conditions after thawing of the medicinal product, see Section 6.3.

6.5. Nature and contents of container

Strength and Age of Individual	Vial Cap and Vial Label Color	Nature and contents of container
30 mcg per dose 12 years and older	Grey	COMIRNATY OMICRON XBB.1.5 dispersion is supplied in a 2 mL clear vial (type I glass) with a stopper (synthetic bromobutyl rubber) and a grey flip-off plastic cap with aluminium seal. One single dose vial contains 1 dose of 0.3 mL, see sections 4.2 and 6.6. One multidose vial (2.25 mL) contains 6 doses of 0.3 mL, see sections 4.2 and 6.6. Single dose vial pack size: 10 vials. Multidose vial pack sizes: 10 vials.

6.6. Special precautions for disposal and other handling

Handling instructions

COMIRNATY OMICRON XBB.1.5 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

Handling prior to use

Frozen vials must be completely thawed prior to use. Frozen vials should be transferred to 2°C to 8°C to thaw. Thaw times for 10-vial packs are noted in table below:

Vial Cap Color	Time That May Be Required For a 10-vial Pack to Thaw (at 2°C to 8°C)
Light Grey	2 hours
Dark Grey	6 hours

- Upon moving frozen vaccine to 2°C to 8°C storage, update the expiry date on the carton. The updated expiry date should reflect 10 weeks from the date of transfer to refrigerated conditions (2°C to 8°C) and not exceeding the original printed expiry date (EXP).
- Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30°C for immediate use.
- If the vaccine is received at 2°C to 8°C (35 ºF to 46 ºF) it should continue to be stored at 2°C to 8°C (35 ºF to 46 ºF). Check that the carton has been previously updated to reflect the 10-week refrigerated expiry date.

- Unopened vials can be stored for up to 12 hours at temperatures up to 30℃. Total storage time between 8 ºC to 30 ºC, inclusive of storage before and after puncture, should not exceed 24 hours.

Preparation for administration

Vial verification

Prior to administration, check the name and strength of the vaccine on the vial label and the color of the vial cap and vial label border to ensure it is the intended presentation. Check whether the vial is a single dose vial or a multidose vial and check if the vial requires dilution.

- Check appearance of vaccine prior to mixing and administration.
  - *Grey cap vials:* Prior to mixing, the vaccine is a while to off-white dispersion and may contain white to off-white opaque amorphous particles.
- Gently invert the vial 10 times. **Do not shake.**
- Do not use the vaccine if particulates or discoloration are present after mixing.

Preparation of individual doses

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw a 0.3 mL single dose.
- *For Dark Grey cap multidose vials (6 doses per vial):*
  - After first puncture, record appropriate date and time on the vial and store at 2 ºC to 30 ºC for up to 12 hours. Do not re-freeze.
  - Each dose must contain 0.3 mL of vaccine. Low dead-volume syringes and/or needles should be used in order to extract all doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters.
  - If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Manufactured by:
Pfizer Manufacturing Belgium NV, Puurs-Sint-Amands, Belgium

Imported by:
PT. Pfizer Indonesia
Jakarta, Indonesia

8. MARKETING AUTHORISATION NUMBER(S)

COMIRNATY ® OMICRON XBB.1.5 Light Grey Cap Box, Single dose vials, 10 vials @ 0.3 mL (Reg. No.:DKIXXXXXX)
COMIRNATY ® OMICRON XBB.1.5 Dark Grey Cap Box, Multiple dose vials, 10 vials @ 2.25 mL (Reg. No.:DKIXXXXXX)

HARUS DENGAN RESEP DOKTER

9. DATE OF REVISION OF THE TEXT

23/04/2026

Leaflet kemasan: Informasi untuk pengguna

Senyawa Obat BNT162b2 Omicron XBB.1.5 mRNA (Vaksin mRNA COVID-19)

COMIRNATY® OMICRON XBB.1.5 30 mikrogram

Baca isi leaflet ini dengan teliti sebelum Anda/anak Anda mulai menggunakan vaksin ini karena berisi informasi penting untuk Anda/anak Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda/anak Anda.
- Vaksin ini hanya diresepkan untuk Anda/anak Anda. Jangan memberikannya kepada orang lain. Vaksin ini dapat membahayakan mereka, sekali pun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda/anak Anda merasakan efek samping apa pun, hubungi dokter, apoteker, atau perawat Anda/anak Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Isi leaflet ini
1. Nama vaksin
2. Bentuk sediaan
3. Deskripsi vaksin
4. Apa kandungan vaksin ini?
5. Kekuatan vaksin
6. Apa kegunaan vaksin ini?
7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan vaksin ini?
8. Kapan seharusnya Anda tidak menggunakan vaksin ini?
9. Apa yang harus dipertimbangkan saat menggunakan vaksin ini?
10. Apa saja obat/vaksin lain atau makanan yang harus dihindari selama menggunakan vaksin ini?
11. Apakah vaksin ini aman untuk ibu hamil dan menyusui?
12. Apakah pasien diperbolehkan mengemudi dan mengoperasikan mesin selama menggunakan vaksin ini?
13. Apa saja potensi efek yang tidak diinginkan dari penggunaan vaksin ini?
14. Bagaimana cara menyimpan vaksin ini?
15. Nomor izin edar
16. Nama dan alamat pemohon dan/atau pemilik vaksin sesuai dengan ketentuan yang berlaku
17. Tanggal revisi
18. Peringatan khusus

1. Nama vaksin

Comirnaty® Omicron XBB.1.5 30 mikrogram/dosis dispersi untuk injeksi

2. Bentuk sediaan

Kekuatan dan Rentang Usia Penerima	Sungkup Vial dan Warna Label Vial	Bentuk Sediaan Farmasi dan Pengenceran Persyaratan	Penyajian (Volume Isi Vial dalam ml dan Jumlah Dosis per Unit)
30 mikrogram per dosis untuk individu berusia 12 tahun ke atas	Abu-abu tua	Dispersi untuk injeksi. Jangan diencerkan.	Vial multidosis (2,25 ml) berisi enam dosis 0,3 ml per vial
	Abu-abu muda	Dispersi untuk injeksi. Jangan diencerkan.	Vial dosis tunggal (0,48 ml) berisi satu dosis 0,3 ml

3. Deskripsi vaksin

Vaksin berupa larutan berwarna putih hingga putih tulang untuk sungkup vial/label berwarna abu-abu.

4. Apa kandungan vaksin ini?

- Bahan aktif dalam Vaksin mRNA COVID-19 disebut raxtozinameran.
- Bahan lainnya adalah:
  - ((4-hidroksibutil)azanediil)bis(heksana-6,1-diil)bis(2-heksildekanoat) (ALC-0315)
  - 2-[(polietilen glikol)-2000]-N,N-ditetradesilasetamid (ALC-0159)
  - 1,2-Distearoil-sn-glisero-3-fosfokolin (DSPC)
  - kolesterol
  - trometamin
  - trometamin hidroklorida
  - sukrosa
  - air untuk injeksi

5. Kekuatan vaksin

30 mikrogram

6. Apa kegunaan vaksin ini?

Comirnaty Omicron XBB.1.5 adalah vaksin yang digunakan untuk mencegah COVID-19 yang disebabkan oleh SARS-CoV-2.

Comirnaty Omicron XBB.1.5 diberikan kepada individu berusia 12 tahun ke atas.

Vaksin tersebut menyebabkan sistem imun (pertahanan alami tubuh) memproduksi antibodi dan sel darah yang bekerja melawan virus, sehingga memberi perlindungan terhadap COVID-19.

Karena Comirnaty Omicron XBB.1.5 tidak mengandung virus untuk memproduksi imunitas, vaksin ini tidak dapat membuat Anda terinfeksi COVID-19.

Penggunaan vaksin ini harus sesuai dengan rekomendasi resmi.

7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan vaksin ini?

Comirnaty Omicron XBB.1.5 diberikan sebagai injeksi 0,3 ml ke dalam otot lengan atas Anda.

Anda akan menerima 1 injeksi, tanpa memandang apakah Anda pernah menerima vaksin COVID-19 sebelumnya.

Jika sebelumnya Anda pernah divaksin dengan vaksin COVID-19, Anda tidak boleh menerima dosis Comirnaty Omicron XBB.1.5 hingga minimal 3 bulan setelah dosis paling akhir.

Jika Anda memiliki gangguan sistem imun, Anda mungkin akan menerima dosis Comirnaty Omicron XBB.1.5 tambahan.

Jika Anda memiliki pertanyaan lebih lanjut mengenai kegunaan Comirnaty Omicron XBB.1.5, tanyakan kepada dokter, apoteker, atau perawat Anda.

8. Kapan seharusnya Anda tidak menggunakan vaksin ini?

Comirnaty Omicron XBB.1.5 tidak boleh diberikan

- jika Anda alergi terhadap bahan aktif atau bahan lain dalam vaksin ini (tercantum dalam bagian 4)

9. Apa yang harus dipertimbangkan saat menggunakan vaksin ini?

Konsultasikan dengan dokter, apoteker, atau perawat Anda sebelum Anda menerima vaksin, jika:

- Anda pernah mengalami reaksi alergi yang berat atau masalah pernapasan setelah injeksi vaksin lain atau setelah Anda diberi vaksin ini sebelumnya.
- Anda merasa gugup menghadapi proses vaksinasi atau pernah pingsan setelah menerima injeksi.
- Anda memiliki penyakit berat atau infeksi dengan demam tinggi. Namun, Anda dapat divaksin jika memiliki demam ringan atau infeksi saluran pernapasan atas, seperti pilek.
- Anda memiliki masalah perdarahan, Anda mudah mengalami lebam, atau Anda menggunakan obat untuk mencegah pembekuan darah.
- Anda memiliki sistem imun yang lemah, karena penyakit seperti infeksi HIV atau memakai obat seperti kortikosteroid yang memengaruhi sistem imun.

Terdapat peningkatan risiko miokarditis (peradangan otot jantung) dan perikarditis (peradangan lapisan luar jantung) setelah divaksin dengan Comirnaty Omicron XBB.1.5 (lihat bagian 13). Kondisi ini dapat muncul hanya dalam beberapa hari setelah vaksinasi dan terutama terjadi dalam waktu 14 hari. Kondisi ini lebih sering teramati setelah vaksinasi kedua, dan lebih banyak dialami oleh laki-laki yang berusia muda. Sebagian besar kasus miokarditis dan perikarditis membaik. Sebagian kasus membutuhkan dukungan perawatan intensif dan telah ditemukan pula adanya kasus fatal. Setelah vaksinasi, Anda harus mewaspadai adanya tanda-tanda miokarditis dan perikarditis, seperti sesak napas, jantung berdebar, dan nyeri dada, dan segera dapatkan pertolongan medis jika hal ini terjadi.

Sama seperti vaksin lainnya, Comirnaty Omicron XBB.1.5 mungkin tidak sepenuhnya melindungi semua orang yang menerimanya dan tidak diketahui berapa lama Anda akan terlindungi.

Efikasi Comirnaty Omicron XBB.1.5 mungkin lebih rendah pada orang-orang dengan gangguan sistem imun. Jika Anda memiliki gangguan sistem imun, Anda mungkin akan menerima dosis Comirnaty Omicron XBB.1.5 tambahan. Jika demikian, Anda harus terus menerapkan tindakan pencegahan fisik untuk membantu mencegah terinfeksi COVID-19. Di samping itu, mereka yang memiliki kontak erat dengan Anda juga harus menerima vaksin yang sesuai. Diskusikan rekomendasi individual yang sesuai dengan dokter Anda.

Anak-anak
Vaksin ini tidak disarankan untuk anak berusia di bawah 12 tahun.

10. Apa saja obat/vaksin lain atau makanan yang harus dihindari selama menggunakan vaksin ini?

Sampaikan kepada dokter atau apoteker jika Anda/anak Anda sedang, belum lama ini, atau mungkin akan menggunakan obat lain atau baru saja menerima vaksin lain.

11. Apakah vaksin ini aman untuk ibu hamil dan menyusui?

Jika Anda/anak Anda sedang hamil atau menduga bahwa Anda/anak Anda mungkin sedang hamil, beri tahu dokter, perawat, atau apoteker Anda sebelum Anda/anak Anda menerima vaksin ini.

Belum ada data yang tersedia mengenai penggunaan Comirnaty XBB.1.5 selama kehamilan. Namun demikian, sejumlah besar informasi dari ibu hamil yang divaksin dengan vaksin Comirnaty yang pertama kali disetujui dalam trimester kedua dan ketiga tidak menunjukkan adanya efek negatif terhadap kehamilan atau bayi yang dilahirkan. Meskipun informasi mengenai efek terhadap kehamilan atau bayi yang dilahirkan setelah menerima vaksinasi dalam trimester pertama masih terbatas, tetapi tidak teramati adanya perubahan terhadap risiko keguguran. Comirnaty Omicron XBB.1.5 dapat digunakan selama kehamilan.

Belum ada data yang tersedia mengenai penggunaan Comirnaty XBB.1.5 selama menyusui. Namun demikian, diperkirakan tidak ada efek terhadap bayi baru lahir/bayi yang menerima ASI. Data yang diperoleh dari ibu menyusui setelah menerima vaksin Comirnaty yang pertama kali disetujui tidak menunjukkan adanya risiko efek merugikan terhadap bayi baru lahir/bayi yang menerima ASI. Comirnaty Omicron XBB.1.5 dapat diberikan selama menyusui.

12. Apakah pasien diperbolehkan mengemudi dan mengoperasikan mesin selama menggunakan vaksin ini?

Beberapa efek vaksinasi yang disebutkan di bagian 13 sementara waktu dapat memengaruhi kemampuan Anda dalam mengoperasikan mesin atau menjalani aktivitas seperti bersepeda. Tunggulah hingga efek ini mereda sebelum melanjutkan aktivitas yang membutuhkan perhatian penuh Anda.

13. Apa saja potensi efek yang tidak diinginkan dari penggunaan vaksin ini?

Sama seperti vaksin lainnya, Comirnaty Omicron XBB.1.5 dapat menimbulkan efek samping, sekalipun tidak semua orang mengalaminya.

Efek samping yang sangat umum: dapat dialami lebih dari 1 di antara 10 orang
- lokasi injeksi: nyeri, bengkak
- kelelahan
- sakit kepala
- nyeri
- menggigil
- nyeri sendi
- diare
- demam

Beberapa efek samping ini sedikit lebih sering terjadi pada remaja berusia 12 hingga 15 tahun dibandingkan pada orang dewasa.

Efek samping yang umum: dapat dialami hingga 1 di antara 10 orang
- kemerahan di lokasi injeksi
- mual
- muntah
- pembesaran kelenjar getah bening (lebih sering teramati setelah dosis booster)

Efek samping yang tidak umum: dapat dialami hingga 1 di antara 100 orang
- tidak enak badan
- nyeri lengan
- susah tidur
- gatal-gatal di lokasi injeksi
- reaksi alergi seperti ruam atau gatal
- merasa lemah atau kurang bertenaga/mengantuk
- penurunan nafsu makan
- pusing
- keringat berlebihan
- berkeringat pada malam hari

Efek samping yang jarang: dapat dialami hingga 1 di antara 1.000 orang
- satu sisi wajah terkulai sementara
- reaksi alergi seperti kaligata atau pembengkakan wajah

Efek samping yang sangat jarang: dapat dialami hingga 1 di antara 10.000 orang
- peradangan otot jantung (miokarditis) atau peradangan lapisan luar jantung (perikarditis) yang dapat menimbulkan sesak napas, jantung berdebar, atau nyeri dada

Tidak diketahui (tidak dapat diperkirakan dari data yang tersedia)
- reaksi alergi yang berat
- pembengkakan yang luas pada anggota gerak yang divaksin
- pembengkakan wajah (pembengkakan wajah dapat terjadi pada pasien yang pernah menerima filler dermatologi wajah)

- reaksi kulit yang menyebabkan bintik-bintik atau bercak-bercak merah di kulit, yang bisa jadi menyerupai target atau sasaran tembak dengan bagian tengah berwarna merah gelap dikelilingi oleh cincin-cincin merah dengan warna yang lebih pucat (eritema multiformis)
- sensasi yang tidak biasa pada kulit, seperti kesemutan atau sensasi merambat (parestesia)
- berkurangnya rasa dan sensitivitas, khususnya pada kulit (hipoestesia)
- perdarahan menstruasi yang berlebihan (sebagian besar kasus tidak bersifat serius dan berlangsung sementara)

Melaporkan efek samping
Jika Anda/anak Anda merasakan efek samping apa pun, hubungi dokter atau, apoteker atau perawat Anda/anak Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih banyak mengenai keamanan vaksin ini.

Untuk melaporkan efek samping, kunjungi situs web www.pfizersafetyreporting.com atau kirimkan email ke IDN.AEReporting@pfizer.com.

14. Bagaimana cara menyimpan vaksin ini?

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Informasi mengenai penyimpanan, kedaluwarsa, serta penggunaan dan penanganan berikut ditujukan bagi petugas kesehatan.

Jangan menggunakan obat ini melebihi tanggal kedaluwarsa yang tertera pada karton dan label setelah tanda EXP. Tanggal kedaluwarsa mengacu pada tanggal terakhir pada bulan tersebut.

Simpan di lemari pembeku bersuhu -90°C hingga -60°C.

Simpan dalam kemasan aslinya untuk melindunginya dari cahaya.

Vaksin ini akan diterima dalam keadaan beku pada suhu -90°C hingga -60°C. Vaksin beku dapat disimpan baik pada suhu -90°C hingga -60°C atau 2°C hingga 8°C saat diterima.

Vial dosis tunggal: Jika disimpan dalam keadaan beku pada suhu -90°C hingga -60°C, paket vaksin dosis tunggal berisi 10 vial dapat dicairkan pada suhu 2°C hingga 8°C selama 2 jam atau vial satuan dapat dicairkan pada suhu ruang (hingga 30°C) selama 30 menit.

Vial multidosis: Jika disimpan dalam keadaan beku pada suhu -90°C hingga -60°C, paket vaksin berisi 10 vial dapat dicairkan pada suhu 2°C hingga 8°C selama 6 jam atau vial satuan dapat dicairkan pada suhu ruang (hingga 30°C) selama 30 menit.

Vial yang dicairkan: Setelah dikeluarkan dari lemari pembeku, vial yang belum dibuka dapat disimpan dan diangkut dengan dimasukkan dalam lemari pendingin pada suhu 2°C hingga 8°C selama 10 minggu; tidak melebihi tanggal kedaluwarsa (EXP) yang tercetak. Kemasan luar harus ditandai dengan tanggal pembuangan baru pada suhu 2°C hingga 8°C. Setelah dicairkan, vaksin tidak boleh dibekukan kembali.

Sebelum digunakan, vial yang belum dibuka dapat disimpan hingga 12 jam antara suhu 8°C hingga 30°C.

Vial yang dicairkan dapat ditangani dalam kondisi cahaya ruang.

Vial yang sudah dibuka: Setelah pertama kali ditusuk, simpan vaksin pada suhu 2°C hingga 30°C dan gunakan dalam waktu 12 jam, termasuk 6 jam waktu pengangkutan. Buang vaksin yang tidak terpakai.

Jangan gunakan vaksin ini jika Anda melihat adanya partikulat atau perubahan warna.

Jangan buang obat melalui saluran pembuangan air atau bersama sampah rumah tangga. Tanyakan kepada apoteker mengenai cara membuang obat yang sudah tidak digunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

15. Nomor izin edar

Comirnaty ® Omicron XBB.1.5 Sungkup Abu-Abu Muda, Dus, Vial dosis tunggal, 10 vial @ 0,3 ml (No. Reg.:DKIXXXXXX)
Comirnaty ® Omicron XBB.1.5 Sungkup Abu-Abu Tua, Dus, Vial multidosis, 10 vial @ 2,25 ml (No. Reg.:DKIXXXXXX)

16. Nama dan alamat pemohon dan/atau pemilik vaksin sesuai dengan ketentuan yang berlaku

Diproduksi oleh:
Pfizer Manufacturing Belgium NV, Puurs-Sint-Amands, Belgia

Diimpor oleh:
PT. Pfizer Indonesia
Jakarta, Indonesia

17. Tanggal revisi

23/04/2026

18. Peringatan khusus

HARUS DENGAN RESEP DOKTER

Informasi berikut ini ditujukan untuk petugas kesehatan saja:

Berikan Comirnaty Omicron XBB.1.5 secara intramuskular sebagai dosis tunggal sebanyak 0,3 ml terlepas dari status vaksinasi COVID-19 sebelumnya.

Untuk individu yang sebelumnya telah menerima vaksin COVID-19, Comirnaty Omicron XBB.1.5 harus diberikan setidaknya 3 bulan setelah dosis vaksin COVID-19 paling akhir.

Dosis tambahan dapat diberikan kepada individu yang mengalami gangguan imun.

Keterlacakan
Untuk meningkatkan keterlacakan produk obat biologis, nama dan nomor batch dari produk yang diberikan harus dicatat dengan jelas.

Penanganan sebelum penggunaan

Vial beku harus dicairkan dengan sempurna sebelum digunakan. Vial beku harus dipindahkan ke suhu 2℃ hingga 8℃ untuk dicairkan. Waktu pencairan untuk satu paket berisi 10 vial tercantum dalam tabel di bawah ini:

Warna Sungkup Vial	**Waktu yang Diperlukan untuk Mencairkan Paket berisi 10 Vial (pada suhu 2℃ hingga 8℃)**
Abu-Abu Muda	2 jam
Abu-Abu Tua	6 jam

- Saat memindahkan vaksin beku ke penyimpanan bersuhu 2℃ hingga 8℃, perbarui tanggal kedaluwarsa pada kemasan. Tanggal kedaluwarsa yang diperbarui harus menunjukkan 10 minggu sejak tanggal pemindahan ke kondisi lemari pendingin (2℃ hingga 8℃) dan tidak melebihi tanggal kedaluwarsa (EXP) asli yang tercetak.
- Sebagai alternatif, vial beku satuan juga dapat dicairkan selama 30 menit pada suhu hingga 30℃ untuk penggunaan segera.
- Jika vaksin diterima pada suhu 2℃ hingga 8℃ (35℉ hingga 46℉), vaksin harus disimpan pada suhu 2℃ hingga 8℃ (35℉ hingga 46℉). Periksa bahwa informasi pada dus telah diperbarui sebelumnya untuk menunjukkan tanggal kedaluwarsa penyimpanan di lemari pendingin selama 10 minggu.
- Vial yang belum dibuka dapat disimpan hingga 12 jam pada suhu maksimal 30℃. Total waktu penyimpanan pada suhu antara 8℃ hingga 30℃, termasuk penyimpanan sebelum dan sesudah ditusuk, tidak boleh melebihi 24 jam.

Persiapan sebelum pemberian

Verifikasi vial

Sebelum pemberian, periksa nama dan kekuatan vaksin yang tertera pada label vial beserta warna sungkup vial dan garis tepi label vial untuk memastikan bahwa vial berisi

sediaan yang dimaksud. Periksa apakah vial merupakan vial dosis tunggal atau vial multidosis dan periksa jika vial perlu diencerkan.

- Periksa penampakan vaksin sebelum dicampur dan diberikan.
    - *Vial sungkup abu-abu:* Sebelum dicampur, vaksin merupakan dispersi berwarna putih hingga putih tulang dan dapat mengandung partikel amorf buram berwarna putih hingga putih tulang.
- Balik perlahan vial sebanyak 10 kali. **Jangan kocok vial.**
- Jangan gunakan vaksin jika terlihat ada partikulat atau perubahan warna setelah dicampur.

Penyiapan dosis satuan

- Dengan menggunakan teknik aseptik, bersihkan sumbat vial dengan tisu antiseptik sekali pakai.
- Ambil dosis tunggal sebanyak 0,3 ml.
- *Untuk vial multidosis dengan sungkup Abu-Abu Tua (6 dosis per vial):*
    - Setelah penusukan pertama vial vaksin, catat tanggal dan waktu yang sesuai pada vial dan simpan pada suhu 2℃ hingga 30℃ selama maksimal 12 jam. Jangan dibekukan kembali.
    - Setiap dosis harus berisi 0,3 ml vaksin. Syringe dan/atau jarum dengan volume rugi rendah harus digunakan untuk mengambil semua dosis dari satu vial. Gabungan syringe dan jarum volume rugi rendah harus memiliki volume rugi tidak lebih dari 35 mikroliter.
    - Jika jumlah vaksin yang tersisa dalam vial tidak dapat memberikan dosis penuh, buang vial beserta volume yang tersisa.

Pembuangan

Produk obat yang tidak terpakai atau limbah harus dibuang sesuai dengan persyaratan setempat.