Generic Name: Tozinameran
Trade Name: Comirnaty Children (5-11 Years)
CDS Effective Date: December 22, 2022
Supersedes: July 26, 2022
Approved by BPOM: March 07, 2023

FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF COMIRNATY® CHILDREN (5-11 YEARS) (FOR AGE 5 YEARS TO <12 YEARS)

Badan POM, the Indonesia Food and Drug Administration, has issued an Emergency Use Authorization (EUA) to permit the emergency use of Comirnaty Children (5-11 Years) 10 micrograms/dose concentrate for dispersion for injection. Comirnaty is a vaccine which may prevent from COVID-19. Read this Fact Sheet for information about Comirnaty prior to providing vaccination.

The Emergency Use Authorization of the Comirnaty Children (5-11 Years) 10 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 5 to <12 years of age. The use of this vaccine should be in accordance with official recommendations.

Comirnaty Children (5-11 Years) is contraindicated in person who is hypersensitive to the active substance or to any of the excipients listed in section **Excipients**.

ADMINISTRATION:

Each dose of 0.2 mL is withdrawn into a syringe for injection to be administered intramuscularly. Do not shake the vial.

The Comirnaty Children (5-11 Years) vaccination primary course consists of two separate doses of **0.2 mL each**. The second dose should be administered between **3 weeks after the first dose** (see section **Dosage and Administration**).

Booster dose in individuals 5 through <12 years of age

A booster dose of Comirnaty Children (5-11 Years) may be administered intramuscularly at least 6 months after the second dose in individuals 5 years through <12 years of age.

Comirnaty Children (5-11 Years) cannot be used in individuals 12 years of age and older.

Interchangeability

The interchangeability of Comirnaty with COVID-19 vaccines from other manufacturers to complete the primary vaccination course or the booster dose has not been established. Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the primary vaccination course and for any additional doses (see section **Dosage and Administration**).

Comirnaty Children (5-11 Years) is available as a concentrate for dispersion for injection. After dilution, one vial (1.3 mL) contains ten (10) doses of 0.2 mL each.

This product contains no preservative.

See the Full EUA Prescribing Information for complete dosage, administration, and preparation instructions.

Health care providers must submit a report on all medication errors and ALL SERIOUS ADVERSE EVENTS related to Comirnaty.

This Fact Sheet may have been updated. For more recent Fact Sheet see www.pom.go.id.

For information on clinical trials that are testing the use of Comirnaty, please see www.clinicaltrials.gov.

INSTRUCTION FOR ADMINISTRATION

This section provides essential information on the use of Comirnaty Children (5-11 Years) 10 micrograms/dose concentrate for dispersion for injection for active immunization to prevent COVID-19 caused by SARS-CoV-2, in individuals 5 to <12 years of age.

Please refer to this fact sheet for information on use of Comirnaty Children (5-11 Years) under the EUA.

Composition

This is a multidose vial and must be diluted before use.

One vial (1.3 mL) contains 10 doses of 0.2 mL after dilution, see section **Dosage and Administration**.

1 dose (0.2 mL) contains 10 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Tozinameran is a 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 SARS-CoV-2.

Concentrate for dispersion for injection (sterile concentrate).

The vaccine is a white to off-white frozen dispersion.

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

Indication

Comirnaty Children (5-11 Years) 10 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 to <12 years of age.

Contraindication
Hypersensitivity to the active substance or to any of the excipients listed in section **Composition**.

Dosage and Administration
Posology
Primary vaccination course
Individuals 5 through <12 years of age
Comirnaty Children (5-11 Years) is administered intramuscularly after dilution as a primary course of 2 doses (0.2 mL each). It is recommended to administer the second dose 3 weeks after the first dose (see sections **SPECIAL WARNINGS AND PRECAUTIONS FOR USE** and **Pharmacodynamic properties**).

Booster dose in individuals 5 through <12 years of age
A booster dose of Comirnaty Children (5-11 Years) may be administered intramuscularly at least 6 months after the second dose in individuals 5 years through <12 years of age.

Comirnaty Children (5-11 Years) cannot be used in individuals 12 years of age and older.

Interchangeability
The interchangeability of Comirnaty with COVID-19 vaccines from other manufacturers to complete the primary vaccination course or the booster dose has not been established. Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the primary vaccination course and for any additional doses.

Individuals may not be protected until at least 7 days after their second dose of the vaccine.

Method of administration
Comirnaty Children (5-11 Years) should be administered intramuscularly after dilution (see section **Instruction for Administration**).

After dilution, vials of Comirnaty Children (5-11 Years) contain 10 doses of 0.2 mL of vaccine. In order to extract 10 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 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

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 **SPECIAL WARNINGS AND PRECAUTIONS FOR USE**.

For instructions regarding thawing, handling and disposal of the vaccine, see section **Instruction for Administration**.

Instruction for Administration
Comirnaty Children (5-11 Years) should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

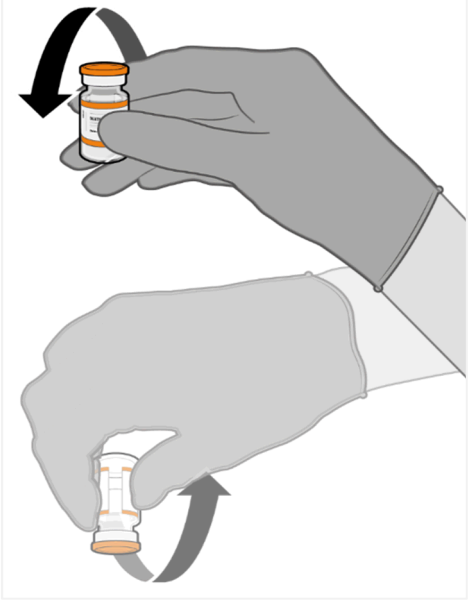
Handling instructions

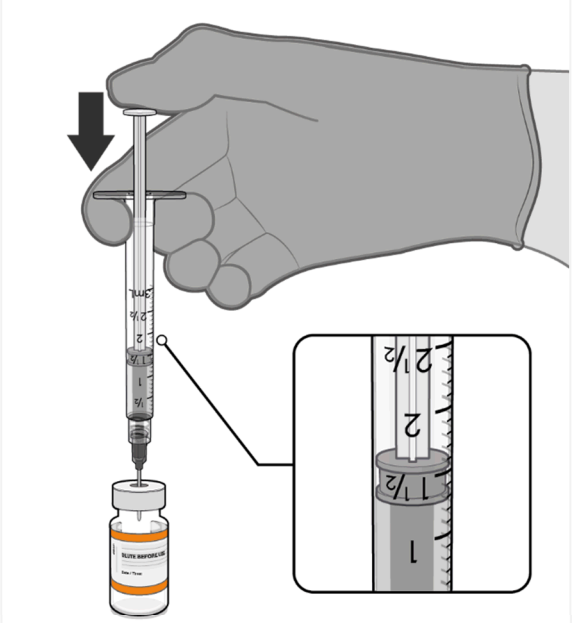
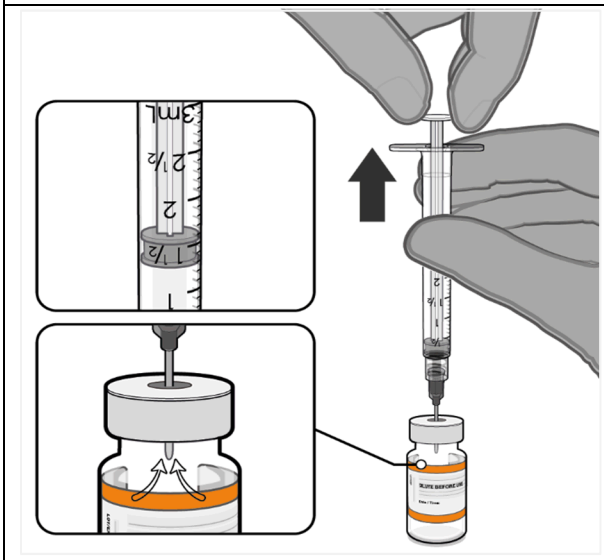
Comirnaty Children (5-11 Years) should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

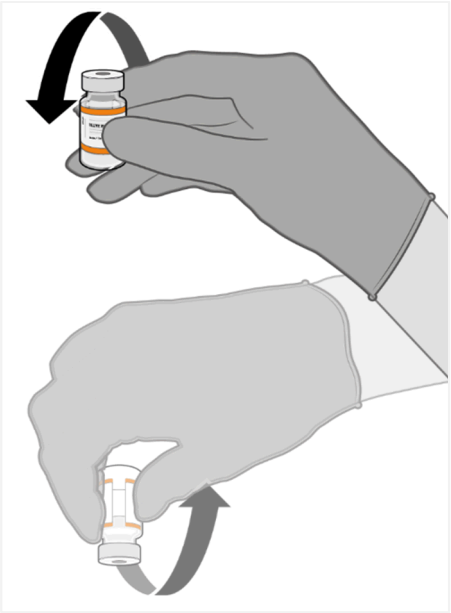
<table>
<tr><th colspan="2">COMIRNATY CHILDREN (5-11 YEARS)</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 

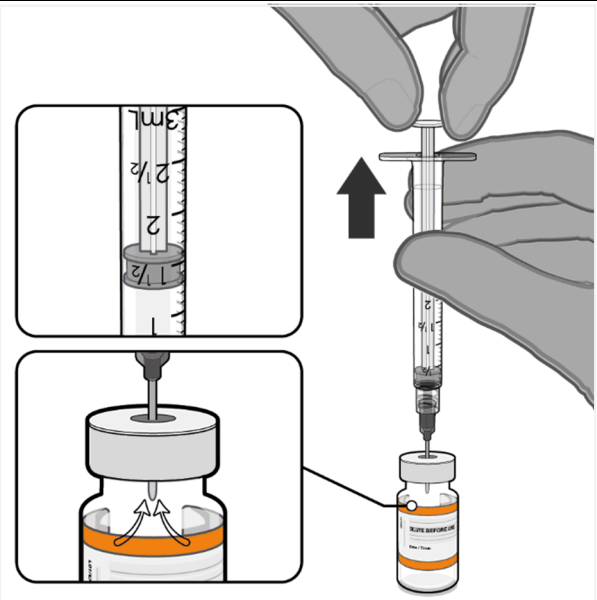
✓ Orange plastic cap and label with orange border.</td><td>• Verify that the vial has an orange plastic cap.</td></tr>
<tr><td colspan="2">HANDLING PRIOR TO USE</td></tr>
<tr><td> 

Store in the refrigerator for up to 10 weeks prior to use.</td><td>• If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use.
• Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP).
• Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C for immediate use.</td></tr>
</table>

COMIRNATY CHILDREN (5-11 YEARS)	
MIXING PRIOR TO DILUTION	
 **Gently × 10**	• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

<table>
<tr><th colspan="2">DILUTION</th></tr>
<tr><td> 
Add 1.3 mL of sterile 0.9% sodium chloride injection</td><td>• The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</td></tr>
<tr><td> 
Pull back plunger to 1.3 mL to remove air from vial.</td><td>• Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.</td></tr>
</table>

 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.
 **Record the date and time of dilution.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2°C to 30°C and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

<table>
<tr><th colspan="2">PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF COMIRNATY CHILDREN (5-11 YEARS)</th></tr>
<tr><td> 

Withdraw 0.2 mL dose of vaccine</td><td>

Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
Withdraw 0.2 mL of COMIRNATY for children age 5 through <12 years.

Low dead-volume syringes and/or needles should be used in order to extract 10 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 standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.
Each dose must contain 0.2 mL of vaccine.
If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
Discard any unused vaccine within 12 hours after dilution.

</td></tr>
</table>

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

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
Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Based on accumulating data, the reporting rates of myocarditis and pericarditis after primary series in children ages 5 through <12 years are lower than in ages 12 through 17 years. Rates of myocarditis and pericarditis in booster doses do not appear to be higher than after the second dose in the primary series. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees 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.

The risk of myocarditis after a third dose of Comirnaty has not yet been characterised.

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, tingling sensations 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 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 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

No interaction studies have been performed.

Concomitant administration of Comirnaty with other vaccines has not been studied.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy
There is limited experience with use of Comirnaty in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section **Preclinical safety data**). Administration of Comirnaty in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Breast-feeding
It is unknown whether Comirnaty is excreted in human milk.

Fertility
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section **Preclinical safety data**).

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Comirnaty has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section **UNDESIRABLE EFFECT** may temporarily affect the ability to drive or use machines.

UNDESIRABLE EFFECT

Summary of safety profile
The safety of Comirnaty was evaluated in participants 5 years of age and older in 3 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age. Study C4591001 (Study 2) enrolled approximately 46,000 participants, 12 years of age or older. Study C4591007 (Study 3) enrolled approximately 2,300 participants 5 through <12 years of age.

Additionally, 306 existing Phase 3 participants at least 18 through 55 years of age received a booster dose of Comirnaty approximately 6 months after the second dose in the non-placebo-controlled booster dose portion of Study 2. The overall safety profile for the booster dose was similar to that seen after 2 doses.

In a subset of Study 3 Phase 2/3 participants, 401 participants 5 through <12 years of age received a booster dose of Comirnaty Children (5-11 Years) at least 5 months after completing the primary series. The overall safety profile for the booster dose was similar to that seen after the primary series.

Children 5 through <12 years of age – after 2 doses
In an analysis of Study 3 (Phase 2/3), 2,268 participants (1,518 Comirnaty 10 mcg; 750 placebo) were 5 through <12 years of age. Of these, 2,158 (95.1%) (1,444 Comirnaty 10 mcg and 714 placebo) participants have been followed for at least 2 months after the second dose. The safety evaluation in Study 3 is ongoing.

The most frequent adverse reactions in children 5 through <12 years of age that received 2 doses included injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).

Children 5 through <12 years of age – after booster dose
In a subset from Study 3, a total of 401 children 5 through <12 years of age received a booster dose of Comirnaty Children (5-11 Years) 10 mcg at least 5 months (range of 5 to 9 months) after completing the primary series. The analysis of the Study 3 (Phase 2/3) subset is based on data up to the cut-off date of March 22, 2022 (median follow-up time of 1.3 months).

The most frequent adverse reactions in participants 5 through <12 years of age were injection site pain (>70%), fatigue (>40%), headache (>30%), myalgia, chills, injection site redness, and swelling (>10%).

Table 1. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 5 Through <12 Years of Age (06 September 2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy	
Immune system disorders			Urticaria[a,b]; Pruritus[a,b]; Rash[a,b]	Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite	
Nervous system disorders	Headache			
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]	Nausea	
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia	Pain in extremity (arm)[a]	

Table 1. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 5 Through <12 Years of Age (06 September 2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Frequency not known (cannot be estimated from the available data)
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Injection site swelling; Injection site redness	Pyrexia	Malaise	

* CIOMS frequency categories are based on clinical trial C4591007 crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in participants 5 through <12 years of age in Study C4591007: angioedema, lethargy, myocarditis, pericarditis, asthenia, hyperhidrosis, and night sweats.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, and rash.

Table 2. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 5 Through <12 Years of Age Who Received Dose 3 (22 March 2022 Data Cut-off Date)†

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders		Lymphadenopathy		
Immune system disorders			Rash[a,b]	Anaphylaxis[a]
Metabolism and nutrition disorders				
Nervous system disorders	Headache			
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]		
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia		

Table 2. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 5 Through <12 Years of Age Who Received Dose 3 (22 March 2022 Data Cut-off Date)†

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Frequency not known (cannot be estimated from the available data)
General disorders and administration site conditions	Injection site pain; Fatigue; Injection site swelling; Injection site redness; Chills	Pyrexia		

* CIOMS frequency categories are based on clinical trial C4591007 crude incidence and was reported to only one significant figure.

† Dose 3 (a booster dose) of BNT162b2 10 µg was administered to participants 5 through <12 years of age in Study C4591007.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in participants 5 through <12 years of age in Study C4591007 after Dose 3: urticaria, pruritus, angioedema, decreased appetite, lethargy, myocarditis, pericarditis, nausea, night sweats, hyperhidrosis, pain in extremity (arm), malaise, and asthenia.

b. The following event is categorized as a hypersensitivity reaction: rash.

Post Authorization Experience

Post authorization ADRs for Comirnaty Children (5-11 Years) have been included in ADR tables above.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, other viral vaccines, ATC code: J07BX03

Mechanism of action

The nucleoside-modified messenger RNA in Comirnaty is formulated in lipid nanoparticles, which enable delivery of the non-replicating RNA into host cells to direct transient 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 in children 5 through <12 years of age – after 2 doses

A descriptive efficacy analysis of Study 3 has been performed in 1,968 children 5 through <12 years of age without evidence of infection prior to 7 days after Dose 2. This analysis evaluated confirmed symptomatic COVID-19 cases accrued up to a data cut-off date of October 8, 2021.

Table 3 presents the specific demographic characteristics in participants who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.

Table 3. Demographics Characteristics – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 – 5 Through <12 Years of Age – Evaluable Efficacy Population

	Comirnaty 10 mcg/dose (N[a]=1305) n[b] (%)	Placebo (N[a]=663) n[b] (%)
Sex		
Male	679 (52.0)	343 (51.7)
Female	626 (48.0)	320 (48.3)
Age at Vaccination		
Mean (SD)	8.2 (1.93)	8.1 (1.98)
Median	8.0	8.0
Min, max	(5, 11)	(5, 11)
Race		
White	1018 (78.0)	514 (77.5)
Black or African American	76 (5.8)	48 (7.2)
American Indian or Alaska Native	<1.0%	<1.0%
Asian	86 (6.6)	46 (6.9)
Native Hawaiian or other Pacific Islander	<1.0%	<1.0%
Other[c]	110 (8.4)	52 (7.8)
Ethnicity		
Hispanic or Latino	243 (18.6)	130 (19.6)
Not Hispanic or Latino	1059 (81.1)	533 (80.4)
Not reported	<1.0%	<1.0%
Comorbidities[d]		
Yes	262 (20.1)	133 (20.1)
No	1043 (79.9)	530 (79.9)

a. N = number of participants in the specified group from the evaluable efficacy population with no evidence of SARS CoV-2 infection prior to 7 days after Dose 2. This value is the denominator for the percentage calculations. Evaluable efficacy population included all eligible randomized participants who received all vaccination(s) as randomized within the predefined window, had no other important protocol deviations as determined by the clinician.
b. n = Number of participants with the specified characteristic.
c. Includes multiracial and not reported.
d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥95th percentile).

The descriptive vaccine efficacy results in children 5 through <12 years of age without evidence of prior SARS-CoV-2 infection are presented in Table 4. None of the cases accrued met criteria for severe COVID-19 or multisystem inflammatory syndrome in children (MIS-C). No cases of COVID-19 were observed in either the vaccine group or the placebo group in participants with evidence of prior SARS-CoV-2 infection.

Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 – Children 5 Through <12 Years of Age Evaluable Efficacy Population

First COVID-19 occurrence from 7 days after Dose 2 in children 5 through <12 years of age without evidence of prior SARS-CoV-2 infection*			
	Comirnaty 10 mcg/dose N[a]=1305 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=663 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
Children 5 through 11 years of age	3 0.322 (1273)	16 0.159 (637)	90.7 (67.7, 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; 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 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 Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.

Immunogenicity in children 5 through <12 years of age – after 2 doses

Study 3 is a Phase 1/2/3 study comprised of an open-label vaccine dose-finding portion (Phase 1) and a multicenter, multinational, randomized, saline placebo-controlled, observer-blind efficacy portion (Phase 2/3) that has enrolled participants 5 through <12 years of age.

In Study 3, an analysis of SARS-CoV-2 50% neutralizing titers (NT50) 1 month after Dose 2 in a randomly selected subset of participants demonstrated effectiveness by immunobridging of immune responses comparing children 5 through <12 years of age in the Phase 2/3 part of Study 3 to participants 16 through 25 years of age in the Phase 2/3 part of Study 2 who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2, meeting the prespecified immunobridging criteria for both the GMR and the seroresponse difference with seroresponse defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from baseline (before Dose 1).

The ratio of the SARS-CoV-2 NT50 in children 5 through <12 years of age to that of young adults 16 through 25 years of age was 1.04 (2-sided 95% CI: 0.93, 1.18), as presented in Table 5.

Table 5. Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Children 5 Through <12 Years of Age (Study 3) to Participants 16 Through 25 Years of Age (Study 2) – Participants Without* Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Comirnaty		5 Through <12 Years/ 16 Through 25 Years	
		10 mcg/Dose 5 Through <12 Years n[a]=264	30 mcg/Dose 16 Through 25 Years n[a]=253		
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Immunobridging Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

* Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. Protocol-specified timing for blood sample collection.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1[5 through <12 years of age] - Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
e. Immunobridging 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.
f. 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.

Among participants without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2, 99.2% of children 5 through <12 years of age and 99.2% of participants 16 through 25 years of age had a seroresponse from before vaccination to 1 month after Dose 2. The difference in proportions of participants who had seroresponse between the 2 age groups (children – young adult) was 0.0% (2-sided 95% CI: -2.0%, 2.2%), as presented in Table 6.

Table 6. Difference in Percentages of Participants With Seroresponse – Participants Without* Evidence of Infection up to 1 Month After Dose 2 – Immunobridging Subset – Phase 2/3 – Comparison of 5 Through <12 Years of Age to Study 2 Phase 2/3 16 Through 25 Years of Age – Evaluable Immunogenicity Population

		Comirnaty			
		Study 3 10 mcg/Dose 5 Through <12 Years N[a]=264	Study 2 30 mcg/Dose 16 Through 25 Years N[a]=253	5 Through <12 Years / 16 Through 25 Years	
Assay	Time Point[b]	n[c] (%) (95% CI[d])	n[c] (%) (95% CI[d])	Difference %[e] (95% CI[f])	Met Immunobridging Objective[g] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[h]	1 month after Dose 2	262 (99.2) (97.3, 99.9)	251 (99.2) (97.2, 99.9)	0.0 (-2.0, 2.2)	Y

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.

* Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

a. N = number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. Protocol-specified timing for blood sample collection.
c. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
e. Difference in proportions, expressed as a percentage (Group 1 [5 through <12 years of age] – Group 2 [16 through 25 years of age]).
f. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
g. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0%.
h. 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.

Immunogenicity in children 5 through <12 years of age – after booster dose

Effectiveness of a booster dose of Comirnaty was based on an assessment of NT50 against the reference strain of SARS-CoV-2 (USA_WA1/2020). Analyses of NT50 1 month after the booster dose compared to before the booster dose (Dose 3) demonstrated a substantial

increase in GMTs in individuals 5 through <12 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose. This analysis is summarized in Table 7.

Table 7. Summary of Geometric Mean Titers – NT50 – Participants Without Evidence of Infection – Phase 2/3 – Immunogenicity Set – 5 Through <12 Years of Age – Evaluable Immunogenicity Population

		Comirnaty 10 mcg/Dose					
		3-Dose Set		2-Dose Set		Total	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1 / Prevax	79	20.5 (20.5, 20.5)	67	20.5 (20.5, 20.5)	146	20.5 (20.5, 20.5)
	2 / 1 Month	29	1659.4 (1385.1, 1988.0)	67	1110.7 (965.3, 1278.1)	96	1253.9 (1116.0, 1408.9)
	3 / Prevax	67	271.0 (229.1, 320.6)	-	-	67	271.0 (229.1, 320.6)
	3 / 1 month	67	2720.9 (2280.1, 3247.0)	-	-	67	2720.9 (2280.1, 3247.0)

Abbreviations: CI = confidence interval; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer; Prevax = before vaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Three-dose immunogenicity set included the first 130 participants who received Dose 3 and completed 1-month post–Dose 3 visit prior to March 15, 2022. Among those, 30 had blood sample collection at 1-month post-Dose 2. Two-dose immunogenicity set included an extra 67 participants randomly selected from previous Dose-2 evaluable immunogenicity population and without evidence of infection up to 1-month post–Dose 2 subset used for 2-dose immunobridging analysis.

Note: Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection up to the 1-month post–Dose 2 (for 1-month post–Dose 2 time point) or 1-month post–Dose 3 (for pre–Dose 3 and 1-month post–Dose 3 time point) study blood sample collection. Having no evidence of past SARS-CoV-2 infection up to 1-month post–Dose 2 was defined as having a negative N-binding antibody (serum) result at the Dose 1 and 1-month post–Dose 2 study visits; a negative NAAT (nasal swab) result at the Dose 1 and Dose 2 study visits and any unscheduled visit prior to the 1-month post–Dose 2 blood sample collection; and no medical history of COVID-19. Having no evidence of past SARS-CoV-2 infection up to 1-month post-Dose 3 was defined as having a negative N-binding antibody (serum) result at the Dose 1, 1-month post–Dose 2 (if available), Dose 3, and 1-month post–Dose 3 study visits; a negative NAAT (nasal swab) result at the Dose 1, Dose 2, and Dose 3 study visits and any unscheduled visit prior to the 1-month post–Dose 3 blood sample collection; and no medical history of COVID-19.

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 dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

Immunogenicity in children 5 through <12 years of age on the Omicron variant – after booster dose

The neutralizing GMTs against both the Omicron variant and reference strain were substantially increased after booster vaccination compared with after the 2-dose primary series. At 1-month post-Dose 2, the observed neutralizing GMTs for the Omicron variant and reference strain were 27.6 and 323.8, respectively. At 1-month post-Dose 3, the observed neutralizing GMTs for the Omicron variant and reference strain were 614.4 and 1702.8, respectively (see Table 8).

For the Omicron variant, neutralizing titers after booster vaccination (1-month post-Dose 3) increased 22-fold over those after the 2-dose primary series (1-month post-Dose 2). For the reference strain, the increase after the booster relative to the primary series was 5.3-fold.

Table 8. Summary of Geometric Mean Titers – Omicron-Neutralization Subset – Participants Without Evidence of Infection – Phase 2/3 – Immunogenicity Set – 5 Through <12 Years of Age – Evaluable Immunogenicity Population

		Comirnaty 10 mcg/Dose	
		Vaccine Group (as Randomized)	
Assay	**Time Point[b]**	**n[b]**	**GMT[c] (95% CI[c])**
SARS-COV-2 FFRNT- B.1.1.529 strain (Omicron) - NT50 (titer)	1 month after Dose 2	29	27.6 (22.1, 34.5)
	1 month after Dose 3	17	614.4 (410.7, 919.2)
SARS-CoV-2 FFRNT- reference strain - NT50 (titer)	1 month after Dose 2	29	323.8 (267.5, 392.1)
	1 month after Dose 3	17	1702.8 (1282.6, 2260.7)

Abbreviations: CI = confidence interval; FFRNT = fluorescence focus reduction neutralization test; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection up to the 1-month post–Dose 2 (for 1-month post–Dose 2 time point) or 1-month post–Dose 3 (for 1-month post–Dose 3 time point) study blood sample collection. Having no evidence of past SARS-CoV-2 infection up to 1-month post–Dose 2 was defined as having a negative N-binding antibody (serum) result at the Dose 1 and 1-month post–Dose 2 study visits; a negative NAAT (nasal swab) result at the Dose 1 and Dose 2 study visits and any unscheduled visit prior to the 1-month post–Dose 2 blood sample collection; and no medical history of COVID-19. Having no evidence of past SARS-CoV-2 infection up to 1-month post–Dose 3 was defined as having a negative N-binding antibody (serum) result at the Dose 1, 1-month post–Dose 2 (if available), Dose 3, and 1-month post–Dose 3 study visits; a negative NAAT (nasal swab) result at the Dose 1, Dose 2, and Dose 3 study visits and any unscheduled visit prior to the 1-month post–Dose 3 blood sample collection; and no medical history of COVID-19.

a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assays at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

Pharmacokinetic properties
Not applicable.

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.

INCOMPATIBILITIES

This medicinal product must not be mixed with other medicinal products except those mentioned in section **Instruction for Administration**.

SHELF-LIFE AND STORAGE CONDITION

Unopened vial
18 months when stored at -90°C to -60°C.

Comirnaty Children (5-11 Years) will 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.

Once removed from frozen storage, the unopened vial may be stored refrigerated at 2 °C to 8 °C for a single period of up to 10 weeks; not exceeding the printed expiry date (EXP).

Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

If the vaccine is received at 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.

When stored frozen at -90 °C to -60 °C, the vaccine can be thawed at either 2 °C to 8 °C or at temperatures up to 30 °C.

Vaccine may be stored at temperatures between 8°C to 30°C for up to 24 hours, including any time at these temperatures following dilution.

Thawed vials can be handled in room light conditions.

Once thawed, the vaccine should not be re-frozen.

Diluted medicinal product
Chemical and physical in-use stability, including during transportation, has been demonstrated for 12 hours at 2 ºC to 30 ºC after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

SPECIAL PRECAUTIONS FOR STORAGE

Comirnaty Children (5-11 Years) can be stored in a refrigerator at 2 °C to 8 °C for a single period of up to 10 weeks, not exceeding the original expiry date (EXP). Alternatively, the vaccine may be stored in a freezer at -90 °C to -60 °C. The expiry date for storage at -90 °C to -60 °C is printed on the vial and outer carton after "EXP".

The vaccine will 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. Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. Check that the expiry date has been updated to reflect the refrigerated EXP date and that the original expiry date has been crossed out.

Store 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.

When stored frozen at -90 °C to -60 °C, the vaccine can be thawed at either 2 °C to 8 °C or at room temperature (up to 30 °C).

Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

NATURE AND CONTENTS OF CONTAINER

1.3 mL concentrate in a 2 mL clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and an orange flip-off plastic cap with aluminium seal. Each vial contains 10 doses, see section **Instruction for Administration**.

Pack size: 10 vials or 195 vials

INSTRUCTIONS FOR HEALTH CARE PROVIDERS

As the health care provider, you must communicate to your patient or parent/caregiver information consistent with the "Informasi untuk Peserta Vaksinasi (Fact Sheet for Vaccinees and Parents/Caregivers)" (and provide a copy of the Fact Sheet) prior to the patient receiving Comirnaty, including:
1. That the Badan POM has authorized emergency use of Comirnaty
2. The potential consequences of refusing Comirnaty
3. The significant known and potential risks and benefits of Comirnaty, as supplied under this EUA.
4. The alternative products that are available and their benefits and risks, including clinical trials.

MANDATORY REQUIREMENTS FOR COMIRNATY COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION:

A. In order to mitigate the risks of using this product under EUA and to optimize the potential benefit of Comirnaty Children (5-11 Years), the following items are required. Use of Comirnaty Children (5-11 Years) under this EUA is limited to the following (all requirements must be met):

1. Comirnaty Children (5-11 Years) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 to <12 years of age.

2. As the health care provider, communicate to your vaccinees or parent/caregiver information consistent with the "Informasi untuk Peserta Vaksinasi" prior to the patient receiving Comirnaty Children (5-11 Years). Health care providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:

a) Given the "Informasi untuk Peserta Vaksinasi",
b) Informed of alternatives to receiving Comirnaty Children (5-11 Years), and
c) Informed that Comirnaty Children (5-11 Years) is an unapproved drug that is authorized for use under Emergency Use Authorization.

3. Subjects with known hypersensitivity to any ingredient of Comirnaty Children (5-11 Years) must not receive Comirnaty Children (5-11 Years).

4. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory responses to requests from Badan POM for information about adverse events and medication errors following receipt of Comirnaty Children (5-11 Years).

5. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and adverse events (death, serious adverse

events*) considered to be potentially related to Comirnaty Children (5-11 Years) occurring after vaccination within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words **"Comirnaty Children (5-11 Years) di bawah Persetujuan Penggunaan Darurat (EUA)"** in the description section of the report.

• Submit adverse event reports to: Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif

Badan Pengawas Obat dan Makanan https://e-meso.pom.go.id/ADR
• Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the statement **"Comirnaty Children (5-11 Years) di bawah Persetujuan Penggunaan Darurat (EUA)"**
*Serious Adverse Events are defined as:
• death;
• a life-threatening adverse event;
• inpatient hospitalization or prolongation of existing hospitalization;
• a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
• a congenital anomaly/birth defect;
• a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

B. The on-going phase 3 trial in Indonesia and or other clinical trial in other countries must be completed as required by the approved clinical trial protocol and clinical trial result must be reported to Badan POM accordingly.

APPROVED AVAILABLE ALTERNATIVES

There are EUAs for other COVID-19 vaccines. The health care provider should visit https://clinicaltrials.gov/ to determine whether the patient may be eligible for enrollment in a clinical trial.

AUTHORITY FOR ISSUANCE OF THE EUA

Indonesian Government has declared an emergency situation as a result of pandemic outbreak of COVID-19 that justifies the emergency need of using Comirnaty Children (5-11 Years) as an option in this situation. In response to that situation, the Badan POM has issued an Emergency Use Authorization (EUA) for the use of Comirnaty Children (5-11 Years) is indicated for a active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 to <12 years of age

As a health care provider, you must comply with the mandatory requirements of the EUA listed above.

Although the phase 3 clinical data is still on going, it is reasonable to believe that Comirnaty Children (5-11 Years) is effective for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 to <12 years of age, as specified in this Fact Sheet. You may be contacted and asked to provide information to help with the assessment of the use of the product during this emergency. Serious adverse events related to the use of Comirnaty Children (5-11 Years) is must be reported to Badan POM through Pusat Farmakovigilans/MESO Nasional, Badan

Pengawas Obat dan Makanan online https://e-meso.pom.go.id/ADR. Please include in the field name, “Describe Event, Problem, or Product Use/Medication Error” the following statement: **Comirnaty Covid-19 Vaccine is di bawah Persetujuan Penggunaan Darurat (EUA)**.

This EUA for Comirnaty Children (5-11 Years) will end when the Badan POM determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

MARKETING AUTHORIZATION NUMBER(S)

Box, 10 multidose vials @ 2 mL (10 x 0.2 mL doses) (Reg No. **EUA2255900143B1**)

HARUS DENGAN RESEP DOKTER

MARKETING AUTHORIZATION HOLDER NAME AND ADDRESS

Manufactured by:
Pfizer Manufacturing Belgium NV., Puurs, Belgium

Released by:
BioNTech Manufacturing GmbH
Kupferbergterrasse 17-19
55116 Mainz
Germany

Imported by:
PT. Pfizer Indonesia
Jakarta, Indonesia

DATE OF REVISION OF THE TEXT

03/2023