**SCHEDULING STATUS: S4**

## 1. NAME OF THE MEDICINE

COMIRNATY READY TO USE ADULT VACCINE 30 micrograms/dose dispersion for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial with a grey cap. Do not dilute prior to use.

One vial (2,25 mL) contains 6 doses of 0,3 mL, see sections 4.2 and 6.6

One dose (0,3 mL) contains 30 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.

Contains sugar (sucrose).

*Excipients with known effect*

Each 0,3 mL dose contains 31 mg sucrose.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Dispersion for injection.

The vaccine is a white to off-white frozen dispersion (pH: 6,9 – 7,9).

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## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

COMIRNATY READY TO USE ADULT VACCINE 30 micrograms/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, 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**

*Primary vaccination course*

*Individuals 12 years of age and older*

COMIRNATY READY TO USE ADULT VACCINE is administered intramuscularly as a primary course of 2 doses (0,3 mL each). It is recommended to administer the second dose 3 weeks after the first dose (see sections 4.4 and 5.1).

*Severely immunocompromised aged 12 years and older*

A third primary course dose may be administered intramuscularly at least 28 days after the second dose to individuals who are severely immunocompromised (see section 4.4).

*Interchangeability*

The interchangeability of COMIRNATY READY TO USE ADULT VACCINE with COVID-19 vaccines from other manufacturers to complete the primary course has not been established. Individuals who have received a dose of COMIRNATY READY TO USE ADULT VACCINE should continue to receive COMIRNATY READY TO USE ADULT VACCINE to complete the primary course.

Doses of COMIRNATY 30 micrograms/dose concentrate for dispersion for injection after dilution (supplied in a vial with a purple cap) and COMIRNATY READY TO USE ADULT VACCINE 30

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micrograms/dose dispersion for injection (supplied in a vial with a grey cap) are considered interchangeable.

*Booster dose*

A booster dose of COMIRNATY READY TO USE ADULT VACCINE should be administered intramuscularly at least 3 months after the primary course with COMIRNATY READY TO USE ADULT VACCINE in individuals 12 years of age and older.

COMIRNATY READY TO USE ADULT VACCINE may also be given as a booster dose in individuals 18 years of age and older who have received a primary course comprised of another mRNA vaccine or adenoviral vector vaccine.

**Special populations**

*Elderly*

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

**Paediatric population**

There is a paediatric formulation available for children 5 to 11 years of age (i.e. 5 to less than 12 years of age). For details, please refer to the professional information for COMIRNATY READY TO USE ADULT VACCINE PAEDIATRIC 10 micrograms/dose concentrate for dispersion for injection.

The safety and efficacy of COMIRNATY READY TO USE ADULT VACCINE in children aged less than 5 years have not yet been established.

**Method of administration**

COMIRNATY READY TO USE ADULT VACCINE 30 micrograms/dose dispersion for injection should be administered intramuscularly (see section 6.6). Do not dilute prior to use.

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Vials of COMIRNATY READY TO USE ADULT VACCINE 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

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 medicines.

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.

**4.3 Contraindications**

Hypersensitivity to COVID-19 mRNA vaccine (nucleoside modified) 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 medicines, the name and the batch number of the administered medicine should be clearly recorded.

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**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 READY TO USE ADULT VACCINE.

*Myocarditis and pericarditis*

There is an increased risk of myocarditis and pericarditis following vaccination with COMIRNATY READY TO USE ADULT VACCINE. 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 suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Medical practitioners 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.

Medical practitioners should consult guidance and/or specialists to diagnose and treat this condition.

The risk of myocarditis after a third dose of COMIRNATY READY TO USE ADULT VACCINE has not yet been characterised.

*Anxiety-related reactions*

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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*

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 READY TO USE ADULT VACCINE may be lower in immunocompromised individuals.

The recommendation to consider a third dose in severely immunocompromised individuals is based on limited serological evidence from a case series in the literature from the clinical management of patients with iatrogenic immunocompromisation after solid organ transplantation (see section 4.2).

*Duration of protection*

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

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*Limitations of vaccine effectiveness*

Vaccination with COMIRNATY READY TO USE ADULT VACCINE may not protect all vaccine recipients.

Individuals may not be fully protected until 7 days after their second dose of vaccine.

**4.5 Interaction with other medicines and other forms of interaction**

No interaction studies have been performed.

Concomitant administration of COMIRNATY READY TO USE ADULT VACCINE with other vaccines has not been studied.

**4.6 Fertility, pregnancy and lactation**

**Pregnancy**

A large amount of observational data from pregnant women vaccinated with COMIRNATY READY TO USE ADULT VACCINE during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). COMIRNATY READY TO USE ADULT VACCINE can be used during pregnancy.

**Breastfeeding**

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of breastfeeding woman to COMIRNATY READY TO USE ADULT VACCINE is negligible. Observational data from women who were breastfeeding after vaccination have not shown a risk for adverse effects in breastfed newborns/infants. COMIRNATY READY TO USE ADULT VACCINE can be used during breastfeeding.

**Fertility**

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

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**4.7 Effects on ability to drive and use machines**

COMIRNATY READY TO USE ADULT VACCINE has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

**4.8 Undesirable effects**

*Summary of the safety profile*

*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 COMIRNATY READY TO USE ADULT 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 READY TO USE ADULT VACCINE.

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 READY TO USE ADULT VACCINE 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 READY TO USE ADULT VACCINE and 7,407 placebo) participants 16 to 55 years of age and a total of 10,540 (5,327 COMIRNATY READY TO USE ADULT VACCINE 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.

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The safety profile in 545 participants 16 years of age and older receiving COMIRNATY READY TO USE ADULT VACCINE, 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 READY TO USE ADULT VACCINE and 1,129 placebo) were 12 to 15 years of age. Of these, 1,559 adolescents (786 COMIRNATY READY TO USE ADULT VACCINE and 773 placebo) have been followed for at least ≥ 4 months after the second dose of COMIRNATY READY TO USE ADULT VACCINE. The safety evaluation in Study 2 is ongoing.

The overall safety profile of COMIRNATY READY TO USE ADULT VACCINE 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 16 years of age and older – after booster dose*

A subset from Study 2 Phase 2/3 participants of 306 adults 18 to 55 years of age who completed the original COMIRNATY READY TO USE ADULT VACCINE 2-dose course, received a booster dose (third dose) of COMIRNATY READY TO USE ADULT VACCINE approximately 6 months (range of 4,8 to 8,0 months) after receiving Dose 2.

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 READY TO USE ADULT VACCINE (5,081

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participants), or placebo (5,044 participants) at least 6 months after the second dose of COMIRNATY READY TO USE ADULT VACCINE. Overall, participants who received a booster dose, had a median follow-up time of 2,5 months after the booster dose to the cut-off date (5 October 2021). No new adverse reactions of COMIRNATY READY TO USE ADULT VACCINE were identified.

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

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

*Tabulated list of adverse reactions from clinical studies and post-authorisation 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 1: Adverse reactions from COMIRNATY READY TO USE ADULT VACCINE clinical trials in individuals 12 years of age and older**

| **System organ class** | **Frequency** | **Adverse reaction** |
|---|---|---|
| *Blood and lymphatic system disorders* | Uncommon | Lymphadenopathy[a] |
| *Immune system disorders* | Uncommon | Hypersensitivity reactions (e.g. rash, pruritus, urticaria[b], angioedema[b]) |
| | Not known | Anaphylaxis |
| *Metabolism and nutrition disorders* | Uncommon | Decreased appetite |

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| | | |
|---|---|---|
| *Psychiatric disorders* | Uncommon | Insomnia |
| *Nervous system disorders* | Very common | Headache |
| | Uncommon | Lethargy |
| | Rare | Acute peripheral facial paralysis[c] |
| *Gastrointestinal disorders* | Common | Nausea |
| *Skin and subcutaneous tissue disorders* | Uncommon | Hyperhidrosis, night sweats |
| *Musculoskeletal and connective tissue disorders* | Very common | Arthralgia, myalgia |
| | Uncommon | Pain in extremity[d] |
| *General disorders and administration site conditions* | Very common | Injection site pain, fatigue, chills, pyrexia[e], injection site swelling |
| | Common | Injection site redness |
| | Uncommon | Asthenia, malaise, injection site pruritus |

a. A higher frequency of lymphadenopathy (5,2 % vs 0,4 %) was observed in participants receiving a booster dose (third dose) compared to participants receiving 2 doses.

b. The frequency category for urticaria and angioedema was rare.

c. 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.

d. Refers to vaccinated arm.

e. A higher frequency of pyrexia was observed after the second dose compared to the first dose.

*Post-marketing side effects*

*Nervous system disorders:* Paraesthesia, hypoaesthesia

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*Cardiac disorders:* Myocarditis, pericarditis

*Gastrointestinal disorders:* Diarrhoea, vomiting

*Skin and subcutaneous tissue disorder:* Erythema multiforme

*General disorders and administration site conditions:* Extensive swelling of vaccinated limb, facial swelling (facial swelling in vaccine recipients with a history of injection of dermatological fillers)

*Description of selected adverse reactions*

*Myocarditis*

The increased risk of myocarditis after vaccination with COMIRNATY READY TO USE ADULT VACCINE 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 READY TO USE ADULT VACCINE. 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 0,57 [95 % CI 0,39 – 0,75] 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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

**4.9 Overdose**

Overdose data is available from 52 study participants included in the clinical trial that due to an error in dilution received 58 micrograms of COMIRNATY READY TO USE ADULT VACCINE. The vaccine recipients did not report an increase in reactogenicity or adverse reactions.

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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, other viral vaccines, ATC code: J07BX03

*Mechanism of action*

The nucleoside-modified messenger RNA in COVID-19 mRNA vaccine (tozinameran) 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 neutralising antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

*Efficacy*

Study 2 is a multicentre, 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. Randomisation 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 hospitalisation for worsening disease during the 6 weeks before enrolment, were included as were participants with known stable infection with human immunodeficiency virus (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 randomised equally and were to receive 2 doses of COVID-19 mRNA vaccine

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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 after Dose 2, 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 medicines or immunoglobulins 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 in total 2,214 person-years for the COVID-19 mRNA vaccine and in total 2,222 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 2.

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**Table 2: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants 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** | **COVID-19 mRNA Vaccine 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 | 8<br>2,214 (17,411) | 162<br>2,222 (17,511) | 95,0<br>(90,0, 97,9) |
| 16 to 64 years | 7<br>1,706 (13,549) | 143<br>1,710 (13,618) | 95,1<br>(89,6, 98,1) |
| 65 years and older | 1<br>0,508 (3,848) | 19<br>0,511 (3,880) | 94,7<br>(66,7, 99,9) |
| 65 to 74 years | 1<br>0,406 (3,074) | 14<br>0,406 (3,095) | 92,9<br>(53,1, 99,8) |
| 75 years and older | 0<br>0,102 (774) | 5<br>0,106 (785) | 100,0<br>(-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.] | | | |

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* 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 nucleic acid amplification tests (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.
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 after Dose 2 in the efficacy population.

The updated vaccine efficacy information is presented in Table 3.

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**Table 3: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection* prior to 7 days after Dose 2 – evaluable efficacy (7 days) population during the placebo-controlled follow-up period**

| Subgroup | COVID-19 mRNA Vaccine 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<br>6,247 (20,712) | 850<br>6,003 (20,713) | 91,3<br>(89,0, 93,2) |
| 16 to 64 years | 70<br>4,859 (15,519) | 710<br>4,654 (15,515) | 90,6<br>(87,9, 92,7) |
| 65 years and older | 7<br>1,233 (4192) | 124<br>1,202 (4226) | 94,5<br>(88,3, 97,8) |
| 65 to 74 years | 6<br>0,994 (3350) | 98<br>0,966 (3379) | 94,1<br>(86,6, 97,9) |
| 75 years and older | 1<br>0,239 (842) | 26<br>0,237 (847) | 96,2<br>(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; diarrhoea; 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

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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.
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 to 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 %) 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.

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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 4) 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 4: 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)* or 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<br>8,439[e] (22,505) | 30<br>8,288[e] (22,435) | 96,7<br>(80,3, 99,9) |
| 7 days after Dose 2[f] | 1<br>6,522[g] (21,649) | 21<br>6,404[g] (21,730) | 95,3<br>(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; diarrhoea; 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);

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- Respiratory failure [defined as needing high-flow oxygen, non-invasive 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-side 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 randomised participants who received at least 1 dose of study intervention.

e. 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 Dose 1 to the end of the surveillance period.

f. Efficacy assessed based on the evaluable efficacy (7 Days) population that included all eligible randomised participants who receive all dose(s) of study intervention as randomised within the predefined window, have no other important protocol deviations as determined by the clinician.

g. 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.

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

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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). 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 non-inferiority 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 (third dose)*

Effectiveness of a booster dose of COVID-19 mRNA Vaccine was based on an assessment of 50 % neutralising antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). In Study 2, analyses of NT50

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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 non-inferiority 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 summarised in Table 5.

**Table 5: SARS-CoV-2 neutralisation assay - NT50 (titer)† (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 non-inferiority objective (Y/N) |
|---|---|---|---|---|---|
| **Geometric mean 50 % neutralising titer (GMT[b])** | 212[a] | 2466,0[b] (2202,6, 2760,8) | 750,6[b] (656,2, 858,6) | 3,29[c] (2,77, 3,90) | Y[d] |
| **Seroresponse rate (%) for 50 % neutralising titer†** | 200[e] | 199[f] 99,5 % (97,2 %, 100,0 %) | 196[f] 98,0 % (95,0 %, 99,5 %) | 1,5 %[g] (-0,7 %, 3,7 %[h]) | Y[i] |

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid

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amplification test; NT50 = 50 % neutralising titer; 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 Microneutralisation Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralisation is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50 % of the virus is neutralised.

* Participants who had no serological or virological evidence (up to 1 month after receipt of a booster dose of COVID-19 mRNA Vaccine ) 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 COVID-19 mRNA Vaccine as initially randomised, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of COVID-19 mRNA Vaccine , 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 titers 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. Non-inferiority 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.

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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. Non-inferiority 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 COVID-19 mRNA Vaccine 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 6. 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 COVID-19 mRNA Vaccine group, and 124 primary cases in the placebo group.

**Table 6: 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*** |
|---|

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| | **COVID-19 mRNA Vaccine N[a]=4695 Cases n1[b] Surveillance Time[c] (n2[d])** | **Placebo N[a]=4671 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<br>0,823 (4659) | 123<br>0,792 (4614) | 95,3<br>(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 COVID-19 mRNA Vaccine booster group relative to the placebo group (non-booster).

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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 COVID-19 mRNA Vaccine 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 ±1 4), or COVID-19 mRNA Vaccine 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 COVID-19 mRNA Vaccine (30 mcg). The boost with COVID-19 mRNA Vaccine induced a 36, 12, and 20 GMR-fold rise in neutralising titres following the Janssen, Moderna, and COVID-19 mRNA Vaccine primary doses, respectively.

Heterologous boosting with COVID-19 mRNA Vaccine 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 COVID-19 mRNA Vaccine booster (n=95).

**Paediatric population**

See section 4.2.

**5.2 Pharmacokinetic properties**

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*Biodistribution results from a luciferase encoding modRNA formulated in the same LNP as BNT162b2, representative of the biodistribution of the modRNA LNP vaccine platform*

After administration of an LNP-formulated luciferase-encoding modRNA to BALB/c mice by intramuscular (IM) injection of 1 µg each in the right and left hind leg (for a total of 2 µg), *in vivo* bioluminescence after injection of luciferin substrate was performed. Luciferase protein expression was detected at different timepoints at the site of injection and to a lesser extent, and more transiently (only seen at 6 hr post-injection), in the liver. Distribution to the liver is likely mediated by LNPs entering the blood stream. The luciferase expression at the injection sites dropped to background levels after 9 days.

The distribution of a LNP with a comparable lipid composition to BNT162b2 but with a surrogate luciferase RNA (monitoring the 3H-CHE lipid label), was investigated in blood, plasma and selected tissues in male and female Wistar Han rats over 48 hours after a single IM injection at 50 µg mRNA/animal. The greatest mean concentration of LNP was found remaining in the injection site at each time point in both sexes. Outside the injection site, low levels of radioactivity were detected in most tissues, with the greatest levels in plasma observed 1 - 4 hours post-dose. Over 48 hours, the LNP distributed mainly to liver, adrenal glands, spleen and ovaries, with maximum concentrations observed at 8 - 48 hours post-dose.

**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 COVID-19 mRNA vaccine (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.

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*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 COVID-19 mRNA vaccine prior to mating and during gestation (receiving 4 full human doses that generate relatively higher levels in rats due to body weight differences, spanning between pre-mating day 21 and gestational day 20). SARS-CoV-2 neutralising 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 COVID-19 mRNA vaccine 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

Trometamol

Trometamol hydrochloride

Sucrose

Water for injections

### 6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6.

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**6.3 Shelf life**

*Unopened vial:*

*Frozen vial:*

9 months when stored at -90 °C to -60 °C.

The vaccine 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.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be stored at room temperature (up to 30 °C) for 30 minutes.

*Thawed vial:*

10 weeks storage and transportation at 2 °C to 8 °C within the 9 month shelf life.

- Upon moving the vaccine 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. 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.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

Thawed vials can be handled in room light conditions.

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

*Handling of temperature excursions during refrigerated storage*

- Stability data indicate that the unopened vial is stable for up to 10 weeks when stored at temperatures from -2 °C to 2 °C, within the 10-week storage period between 2 °C and 8 °C.
- Stability data indicate the vial can be stored for up to 24 hours at temperatures of 8 °C to 30 °C,

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including up to 12 hours following first puncture.

This information is intended to guide health care providers only in case of temporary temperature excursion.

*Opened vial*

Chemical and physical in-use stability has been demonstrated for 12 hours at 2 ºC to 30 ºC, which includes up to 6 hours transportation time. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the vaccine should be used immediately. If not used immediately, in use storage times and conditions are the responsibility of the user.

**6.4 Special precautions for storage**

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

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

For storage conditions after thawing and first opening, see section 6.3.

**6.5 Nature and contents of container**

2,25 mL solution in a 2 mL clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and a grey flip off plastic cap with aluminium seal. Each vial contains 6 doses, see section 6.6.

Pack size: 195 vials or 10 vials.

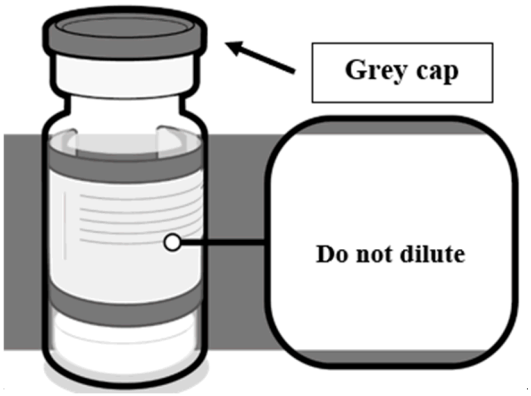
Not all pack sizes may be marketed.

**6.6 Special precautions for disposal and other handling**

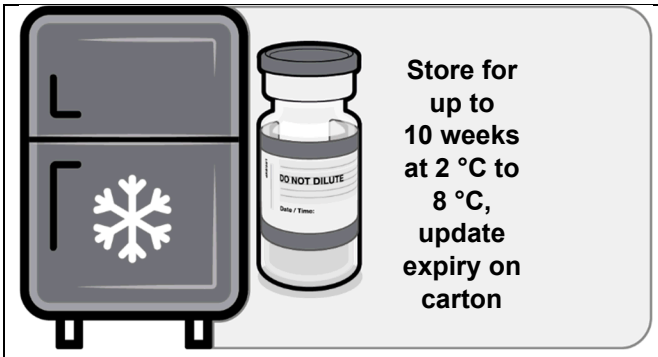
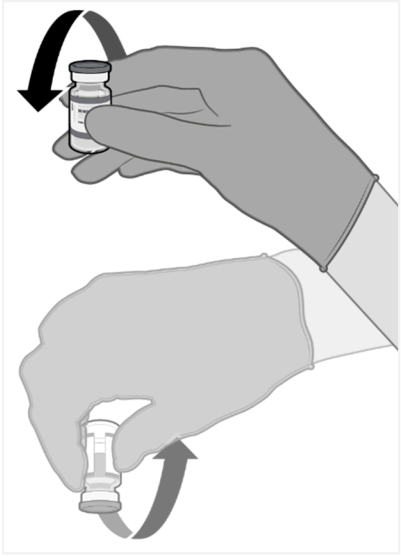
*Handling instructions*

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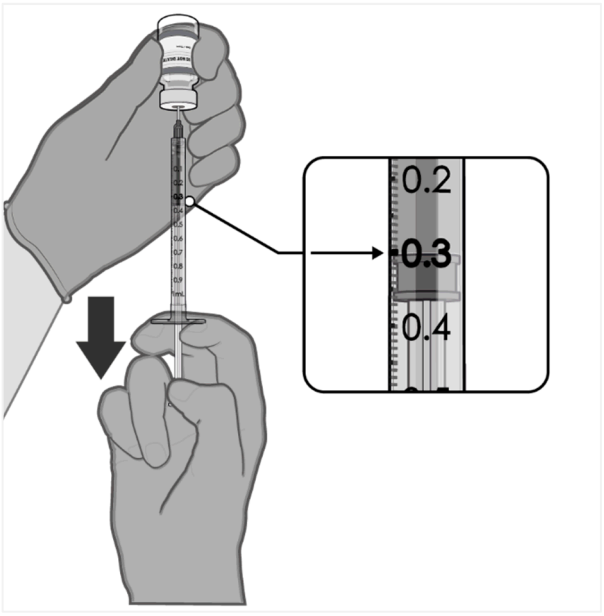
COMIRNATY READY TO USE ADULT VACCINE should be prepared by a health care provider using aseptic technique to ensure the sterility of the prepared dispersion.

<table>
<tr><th colspan="2">VIAL VERIFICATION OF COMIRNATY READY TO USE ADULT VACCINE 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)</th></tr>
<tr><td>
</td><td>• Verify that the vial has a grey plastic cap and a grey border around the label and the product name is COMIRNATY READY TO USE ADULT VACCINE 30 micrograms/dose dispersion for injection.<br>• If the vial has a purple plastic cap, please make reference to the professional information for COMIRNATY 30 micrograms/dose concentrate for dispersion for injection.<br>• If the vial has an orange plastic cap, please make reference to the professional information for COMIRNATY READY TO USE ADULT VACCINE PAEDIATRIC 10 micrograms/dose concentrate for dispersion for injection.</td></tr>
<tr><th colspan="2">HANDLING PRIOR TO USE OF COMIRNATY READY TO USE ADULT VACCINE 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER))</th></tr>
<tr><td></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</td></tr>
</table>

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<table>
<tr>
<td>
</td>
<td>10-vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use.<br>• Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.<br>• Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C not exceeding the printed expiry date (EXP).<br>• Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C.<br>• Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.</td>
</tr>
<tr>
<td><br>Gently × 10</td>
<td>• Gently mix by inverting vials 10 times prior to use. Do not shake.<br>• Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.<br>• After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.</td>
</tr>
<tr>
<td colspan="2">PREPARATION OF INDIVIDUAL 0,3 mL DOSES OF COMIRNATY READY TO USE ADULT VACCINE 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)</td>
</tr>
</table>

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<table>
<tr>
<td>

0,3 mL vaccine</td>
<td>
<ul>
<li>Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.</li>
<li>Withdraw 0,3 mL of COMIRNATY READY TO USE ADULT VACCINE.<br><br>Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.<br><br>If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</li>
<li>Each dose must contain 0,3 mL of vaccine.</li>
<li>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.</li>
<li>Discard any unused vaccine 12 hours after first puncture. Record the appropriate date/time on the vial.</li>
</ul>
</td>
</tr>
</table>

*Disposal*

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

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## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0) 11 320 6000 / 0860 734 937 (Toll-free South Africa)

## 8. REGISTRATION NUMBER

56/30.2/1179

## 9. DATE OF FIRST AUTHORISATION

15 November 2022

## 10. DATE OF REVISION OF THE TEXT

To be advised.

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