COMIRNATY® is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). The mRNA instructs the cell to produce proteins of the S antigen (a piece of the spike protein unique to SARS-CoV-2) to stimulate an immune response. Efficacy shown in clinical trials in participants with or without evidence of prior infection with SARS-CoV-2 and who received the full series of vaccine (2 doses) was approximately 95% based on a median follow-up of two months.

**Date of WHO Emergency Use Listing (EUL) recommendation:** 31 December 2020

**Date of prequalification (PQ):** currently no information
National regulatory authorities (NRAs) can use reliance approaches for in-country authorization of vaccines based on WHO PQ/EUL or emergency use authorizations by stringent regulatory authorities (SRAs).

**Product characteristics**

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Frozen, sterile, preservative-free, multi-dose concentrate for dilution before administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses</td>
<td>One vial (0.45 mL) contains 6 doses of vaccine after dilution</td>
</tr>
</tbody>
</table>
| Vaccine syringe type and needle size | Auto-disable (AD) syringe: 0.3 mL
Needle for intramuscular injection 23G × 1” (0.60 × 25 mm) |

**Schedule and administration**

| Recommended for age | 16 years of age and older
Vaccination is recommended for older persons without an upper age limit |
|---------------------|---------------------------------------------------------------------|
| Recommended schedule | 2 doses at a recommended interval of 21–28 days:
Dose 1: at the start date
Dose 2: 21–28 days after first dose |
|                      | If the second dose is accidentally administered earlier than 21 days, the dose does not need to be repeated. Delay of the second dose should not exceed 42 days (6 weeks), in the event of limited supply. Both doses are necessary for protection. |
| Route and site of administration | Intramuscular (i.m.) administration
The preferred site is deltoid muscle. |

\(^1\)Contents will be updated as new information becomes available.
**Dosage**
0.3 mL (single dose after dilution)

**Diluent**
0.9% sodium chloride solution for injection, unpreserved, in a 10 mL vial for single use
1.8 mL diluent required per 6 dose vaccine vial

**Mixing syringe**
Reuse prevention (RUP) syringe: 3 mL (5 mL RUP syringe acceptable)
Needle: 21G or narrower

**Reconstitution/dilution required**
- **Thaw before dilution:**
  - Before dilution, vials must reach room temperature and be diluted within 2 hours.
  - Thaw vaccine up to 3 hours at +2 to +8 °C in refrigerator or for 30 minutes at 25 °C before dilution.

- **Dilute before use:**
  1. Before dilution, invert vaccine vial gently 10 times, **do not shake**.
  2. Draw into the mixing syringe 1.8 mL of diluent.
  3. Add 1.8 mL of diluent into the vaccine vial; level/equalize the pressure in the vial before removing the needle by withdrawing 1.8 mL of air into the empty diluent syringe.
  4. Discard diluent syringe in safety box (do not reuse) and discard diluent vial.
  5. Gently invert the vial with diluted vaccine 10 times to mix; **do not shake**.
  6. Inspect to make sure that the vaccine is an off-white uniform suspension; do not use if discoloured or if containing particles.
  7. Record date and time of dilution on the vaccine vial label.
  8. Draw up the vaccine dose at the time of administration, pre-loading vaccine into syringes is not recommended. Use all vaccine within 6 hours after dilution.

**Multi-dose vial policy**
Discard any unused vaccine 6 hours after dilution, or at the end of the immunization session, whichever comes first.

**Contraindications**
- Known history of a severe allergic reaction (e.g. anaphylaxis) to any component of COMIRNATY® vaccine. In particular, COMIRNATY® should not be administered to individuals with a known history of severe allergic reaction to polyethylene glycol (PEG) or related molecules.
- Persons with an immediate allergic reaction (e.g. anaphylaxis, urticaria, angioedema, respiratory distress) to the first dose of COMIRNATY® should not receive additional doses.

**Precautions**
- For persons with known history of any immediate allergic reaction to any other vaccine or injectable therapy, a risk assessment should be conducted to determine type and severity of reaction. They may still receive vaccination but they should be counseled about the risks of developing a severe allergic reaction. The risks should be weighed against the benefits of vaccination. Such persons should be observed for 30 minutes after vaccination.
- Food, contact or seasonal allergies, including to eggs, gelatin and latex, are not considered precautions or contraindications.
- Vaccination of people suffering from acute severe febrile illness (body temperature over 38.5 °C) or acute infection, including symptomatic SARS-CoV-2 infection, should be deferred until they have recovered from acute illness.
**COMIRNATY®, COVID-19 mRNA vaccine**

### Special population groups (based on available data as of January 2021)

- **For persons with comorbidities** (e.g. hypertension, diabetes, asthma, and stable and well controlled infections such as hepatitis B or C) that have been identified as increasing the risk of severe COVID-19, vaccination is recommended.
- **Available data on administration in pregnant women** are insufficient to inform vaccine-associated risks in pregnancy. Vaccination is not currently recommended during pregnancy unless the benefit of vaccinating (e.g. health workers at high risk of exposure and pregnant women with comorbidities) outweighs the potential vaccine risks. WHO does not recommend pregnancy testing prior to vaccination.
- **There are no data on the safety of COMIRNATY® for breastfeeding women** or on the effects on breastfed child. As this is not a live virus vaccine and the mRNA does not enter the nucleus of the cell and is degraded quickly, it is therefore biologically and clinically unlikely to pose a risk to the breastfeeding child. A lactating woman who is a part of a group recommended for vaccination should be offered vaccination. WHO does not recommend discontinuing breastfeeding after vaccination.
- **Immunocompromised persons** may have diminished immune response to vaccine. Nevertheless, if part of a recommended group for vaccination, they may be vaccinated. Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised persons should be provided to inform individual benefit–risk assessment.
- **Persons with autoimmune conditions** who have no contraindications to vaccination may be vaccinated.
- **HIV-positive persons** who are well controlled on highly active antiretroviral therapy and are part of a group recommended for vaccination can be vaccinated. Available data for HIV-positive persons who are not well controlled on therapy are currently insufficient to allow assessment of vaccine efficacy and safety in this group.
- **Persons with a history of Bell’s palsy** may receive COMIRNATY® if no contraindications. Currently there is no conclusive evidence that observed cases were causally related to vaccination.
- **For persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment**, vaccination should be deferred for at least 90 days to avoid interference of treatment with vaccine-induced immune response.

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**Schedule and administration contd.**

- For persons with **comorbidities** (e.g. hypertension, diabetes, asthma, and stable and well controlled infections such as hepatitis B or C) that have been identified as increasing the risk of severe COVID-19, vaccination is recommended.
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## Stability and storage

| Vaccine storage temperature | Ultra-low temperatures:  
• at -80 to -60 °C in freezer, or  
• at -90 to -60 °C in thermal shipper as temporary storage for up to 30 days from delivery (should be re-iced every 5 days if opened up to 2 times a day, less than 3 minutes at a time) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent storage temperature</td>
<td>Room temperature (up to 30 °C)</td>
</tr>
</tbody>
</table>
| Shelf life at different temperatures | **Undiluted vaccine at storage temperature** -90 to -60 °C: 6 months after the time of manufacturing  
**Undiluted thawed** vaccine at +2 to +8 °C: up to 120 hours (5 days) prior to dilution  
**Undiluted thawed** vaccine at temperatures up to +30 °C: up to 2 hours  
**Diluted** vaccine at +2 to +30 °C: 6 hours after dilution |
| Freeze sensitivity | Do not refreeze thawed vials.  
Do not freeze diluted vaccine. |
| Light sensitivity | Minimize exposure to room light.  
Avoid exposure to direct sunlight and ultraviolet light. |
| Conditions before use | At room temperature (up to 30 °C) before dilution and use |
| Wastage rates | Will be dependent on country context. |
| Buffer stock needed | Will be dependent on country context. |

## Labelling and packaging

For AMC92 countries, UNICEF will supply vaccines and diluents (10 mL vials for single use).

<table>
<thead>
<tr>
<th>Vaccine Vial Monitor (VVM) (if yes, where located and type)</th>
<th>Initial pandemic supply will not include a VVM.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling information on vial label (QR code, datamatrix, barcode) and type of information embedded on them</td>
<td>Not finalized</td>
</tr>
<tr>
<td>Labelling information on secondary packaging (QR code, datamatrix, barcode) and type of information embedded on them</td>
<td>Not finalized</td>
</tr>
<tr>
<td>Labelling information on tertiary packaging (QR code, datamatrix, barcode) and type of information embedded on them</td>
<td>Not finalized</td>
</tr>
</tbody>
</table>
| Secondary packaging dimension and volume | Trays holding 195 vials/1170 doses  
229 × 229 × 40 mm = 1.8 cm³/dose |
| Tertiary packaging dimension and volume | Insulated box containing 5 secondary cartons with a total of 975 vials  
(5850 doses)  
External dimensions 400 × 400 × 560 mm |
COMIRNATY®, COVID-19 mRNA vaccine

**Safety information***

<table>
<thead>
<tr>
<th>Possible events (by frequency)</th>
<th>Very common (≥1/10): Headache, arthralgia, myalgia, injection site pain, fatigue, chills, pyrexia (higher frequency after 2nd dose), injection site swelling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Common (≥1/100 to &lt;1/10): Nausea, injection site redness</td>
</tr>
<tr>
<td></td>
<td>Uncommon (≥1/1 000 to &lt;1/100): Lymphadenopathy, insomnia, pain in extremity, malaise, injection site itching</td>
</tr>
<tr>
<td></td>
<td>Rare (≥1/10 000 to &lt; 1/1 000): Bell’s palsy (acute peripheral facial paralysis)</td>
</tr>
<tr>
<td></td>
<td>Not known (cannot be estimated from available data): Anaphylaxis, hypersensitivity</td>
</tr>
</tbody>
</table>

**Co-administration of vaccines/medicines**

There should be a minimum interval of 14 days between administration of this and any other vaccine against other diseases, until data on co-administration become available.

*From clinical studies

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**Important reminders**

**Vaccination session and vaccine administration:**

Before, during, and after vaccination, all people should continue to follow current guidance for protection from COVID-19 in their area (e.g. wearing a mask, keeping physical distance, hand hygiene).

A person presenting with COVID-19 symptoms should not be vaccinated. Vaccination may be offered to people who have recovered from COVID-19, whether symptomatic or asymptomatic.

This vaccine should only be administered in settings where appropriate medical treatment to manage anaphylaxis is immediately available, hence, in settings with the necessary resources and trained health workers, and in setting that allow for at least 15 minutes of post vaccination observation. (For more information on AEFI kits and treatment, please refer to the training materials – COVID-19 vaccination training for health workers, Module 4: AEFI monitoring).

Before vaccination, advise vaccine recipient about possible post vaccination symptoms and observe post vaccination for at least 15 minutes.

Persons with history of allergic reactions should be observed 30 minutes post vaccination.

To alleviate post vaccination symptoms, antipyretic or analgesics may be taken (routine prophylaxis to prevent the symptoms is not recommended due to lack of information on impact on immune response).

Encourage a vaccine recipient to complete the vaccination series to optimize protection and schedule the time for the second dose. The same vaccine product should be used for both doses.
COMIRNATY®, COVID-19 mRNA vaccine

Important reminders contd.

Special storage and handling precaution:

Closed-lid vial trays removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for a maximum of 5 minutes when transferring from one ultra-low temperature environment to another. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

Open-lid vial trays, or trays with less than 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for a maximum of 3 minutes when removing a number of vials needed for the vaccination session or when transferring from one ultra-low temperature environment to another. Once a vial is removed from the vial tray, it should be thawed for use. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

Resources and more information at:

https://www.pfizer.com/science/coronavirus
https://biontech.de/covid-19