



INFORMATION SHEET

PFIZER-BIONTECH COVID-19 VACCINE

COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified)

WHAT IS COVID-19 DISEASE?

COVID-19 is a viral disease that mainly affects respiratory system but may also affects the other organs such as the heart, kidney, blood vessels etc. People above 60 years of age and those with underlying conditions such as heart, lung, liver, kidney diseases, those with immunocompromised state, diabetes, pregnancies etc. may have more severe presentation and outcome.

SARS-Cov-2 is highly infectious and can be transmitted through respiratory route and by contact. A person may develop symptoms within 1 to 14 days after exposure. Person can transmit the virus 2 days before the symptom onset and upto 10 days after symptom onset or more, depending on severity of presentation and immune status. About 40% of people may not develop any symptoms though they are able to transmit the infection. Common symptoms include, sore throat, runny nose, cough, fever, shortness of breath, headache, body ache, loss of smell/taste, diarrhoea, and vomiting.

If a person develops COVID-19 like symptoms, they should self-isolate and visit a flu clinic and get tested. COVID-19 PCR test can detect the infection.

To minimize the chance of catching the virus, it is advisable to follow all preventive measures such as wearing masks, physical distancing (at least 3 feet distance), frequent hand washing, cleaning and disinfection of surfaces and ensure good ventilation of premises.

WHAT ARE THE BENEFITS OF VACCINATION?

Vaccination protects the person taking the vaccine and the community. When more people are vaccinated it prevents community transmission and protects those who cannot take the vaccine like young children etc. Two doses of vaccine are required to attain full protection.

The vaccine decreases development of severe COVID-19 disease and will decrease risk of hospitalization and also help in reducing spread of Covid-19 disease. However, there may be a chance that you might still get or spread infection even after vaccination. Therefore, it is important to wear mask and follow the social distancing guidance and other preventive measures.

WHAT PFIZER-BIONTECH COVID-19 VACCINE (COMIRNATY) IS AND WHAT IT IS USED FOR

Pfizer-BioNTech COVID-19 Vaccine (Comirnaty) is used for preventing COVID-19 caused by SARS-CoV-2 virus.

Pfizer-BioNTech COVID-19 Vaccine is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defenses) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Pfizer-BioNTech COVID-19 Vaccine does not contain the virus to produce immunity, it cannot give you COVID-19.

Pfizer-BioNTech COVID-19 Vaccine (Comirnaty) contains.

- The active substance is COVID-19 mRNA Vaccine. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms mRNA each.
- The other ingredients are:
 - ((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
 - potassium chloride
 - potassium dihydrogen phosphate
 - sodium chloride
 - disodium phosphate dihydrate
 - sucrose
 - water for injections

WHO CAN RECEIVE THIS VACCINE

Pfizer-BioNTech COVID-19 Vaccine is licensed by the Maldives Food and Drug Authority in people aged ≥12 years. Maldives Technical Advisory Group on Immunization (MTAGI) recommends for all people aged 12 years and older can receive Pfizer-BioNTech COVID-19 Vaccine

WHO SHOULD NOT RECEIVE THIS VACCINE

You should not receive this vaccine if you have had:

- anaphylaxis (a type of severe allergic reaction) to a previous dose of the vaccine
- anaphylaxis after exposure to any component of the vaccine, including polyethylene glycol (PEG)
- myocarditis and/or pericarditis attributed to a previous dose of the vaccine
- any other serious adverse event attributed to a previous dose of the vaccine

PRECAUTIONS FOR VACCINATION

People with certain conditions may need additional precautions such as staying for 30 minutes of observation after having their vaccine or consulting an allergy specialist. Tell your immunization provider if you have had:

- an allergic reaction to a previous dose of a COVID-19 vaccine or to an ingredient of the vaccine
- anaphylaxis to other vaccines or to other medicines. Your provider can check to ensure there are no common ingredients with the COVID-19 vaccine you are receiving
- confirmed mastocytosis with recurrent anaphylaxis that requires treatment.

If you have a bleeding disorder or you are taking a blood-thinning medication (anticoagulant), tell your immunization provider. Your immunization provider can help determine whether it is safe for you to have an intramuscular injection and help decide the best timing for injection.

SPECIAL CIRCUMSTANCES TO DISCUSS BEFORE VACCINATION

People with precautionary conditions for Pfizer-BioNTech COVID-19 Vaccine

People with a history of any of the following conditions can receive Pfizer-BioNTech COVID-19 Vaccine but advice should be sought from a cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis
- Acute rheumatic fever
- Dilated cardiomyopathy (for people under 30 years of age)
- Congenital heart disease
- Severe heart failure
- Heart transplant recipients

People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition that weakens their immune system. It also includes those who may be taking medications that suppress their immune system.

The Health Protection Agency strongly recommends people with immunocompromise receive COVID-19 vaccination. Pfizer-BioNTech COVID-19 Vaccine is not a live vaccine. It is safe in people with immunocompromise.

People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death.

Clinical trials for Pfizer-BioNTech COVID-19 Vaccine did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Pfizer-BioNTech COVID-19 Vaccine is as effective in people with immunocompromise compared to the rest of the population. It is possible that Pfizer-BioNTech COVID-19 Vaccine might not be as effective in people with immunocompromise as it is in the general population. It is important to continue other preventative measures such as physical distancing after vaccination.

Women who are pregnant or breastfeeding

Pregnant women should be routinely offered Pfizer-BioNTech COVID-19 Vaccine at any stage of pregnancy. If you are trying to become pregnant you do not need to delay vaccination or avoid becoming pregnant after vaccination.

Pregnant women with COVID-19 have an increased risk of severe illness and adverse pregnancy outcomes. Real-world evidence has shown that Pfizer-BioNTech COVID-19 Vaccine is safe for pregnant women and breastfeeding women.

If you are breastfeeding, you can have Pfizer-BioNTech COVID-19 Vaccine. You do not need to stop breastfeeding after vaccination.

People with a history of COVID-19

If you have had COVID-19 in the past, tell your immunization provider. Your provider may advise to wait for up to 28 days after recovery before having a COVID-19 vaccine. If you have ongoing illness from COVID-19, discuss the best timing of vaccination with your treating doctor.

Children

Pfizer-BioNTech COVID-19 Vaccine is not recommended for children aged under 12 years.

HOW PFIZER-BIONTECH COVID-19 VACCINE IS GIVEN

Pfizer-BioNTech COVID-19 Vaccine is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks (21 days) after the first dose to complete the vaccination course.

If you have any further questions on the use of Pfizer-BioNTech COVID-19 Vaccine, ask your doctor, nurse, or public health specialist.

POSSIBLE SIDE EFFECTS

Like all vaccines, Pfizer-BioNTech COVID-19 Vaccine can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea
- fever

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people

- injection site redness
- nausea
- vomiting

Uncommon side effects: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching

Rare side effects: may affect up to 1 in 1,000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

REPORTING OF SIDE EFFECTS

If you get any side effects, talk to your doctor, or nurse. This includes any possible side effects not listed in this information sheet.

The safety of COVID-19 vaccines will be monitored continuously throughout the COVID-19 vaccination program.

You can report suspected side effects to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to health care center/ hospital or directly to the National Immunization Program (NIP), Health Protection Agency.

If you would prefer to report it yourself, please call 1676 for information on how to report suspected side effects associated with COVID-19 vaccines.

Note: If you have any queries regarding Covid-19 vaccine, please email to vaccine@health.gov.mv

HOW TO STORE PFIZER-BIONTECH COVID-19 VACCINE

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C. Within the 6 months shelf-life unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C.

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

Once a vial is removed from the vial tray, it should be thawed for use.

After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 1 month (31 days) at 2 °C to 8 °C. Within the 1 month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C.

After dilution, store and transport the vaccine at 2 °C to 30 °C and use **within 6 hours**. Discard any unused vaccine.

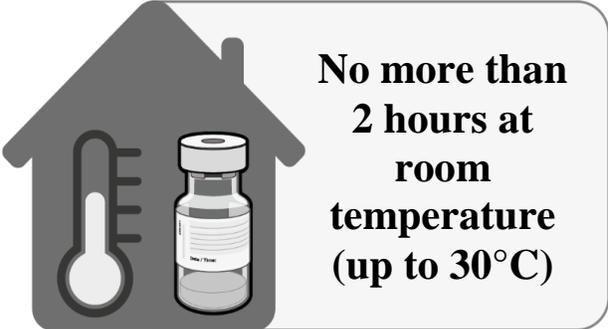
Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.

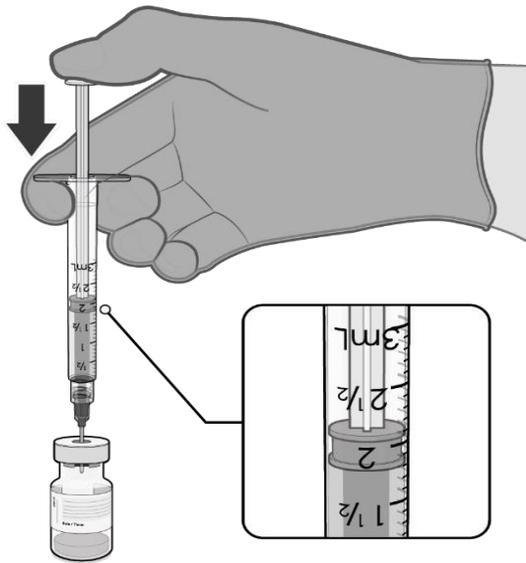
Do not use this vaccine if you notice particulates in the dilution or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your immunization provider how to throw away medicines you no longer use. These measures will help protect the environment.

HANDLING INSTRUCTION FOR VACCINATOR

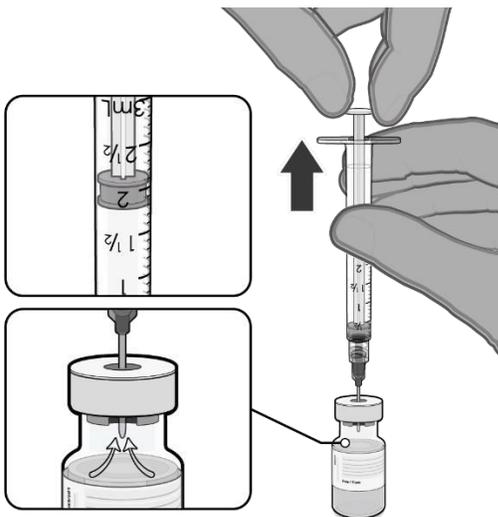
Pfizer-BioNTech COVID-19 Vaccine (Comirnaty) should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

THAWING PRIOR TO DILUTION	
 <p>No more than 2 hours at room temperature (up to 30°C)</p>	<ul style="list-style-type: none">• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.• The unopened vial can be stored for up to 1 month at 2 °C to 8 °C. Within the 1 month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.• 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.
DILUTION	



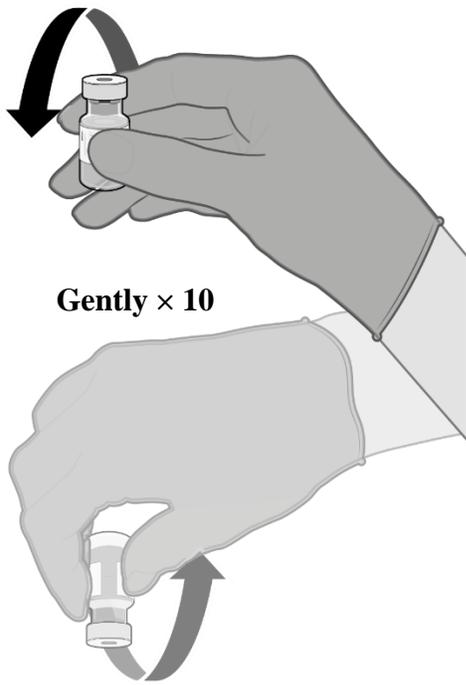
1.8 mL of 0.9% sodium chloride injection

- The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



Pull back plunger to 1.8 mL to remove air from vial.

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.



Gently × 10

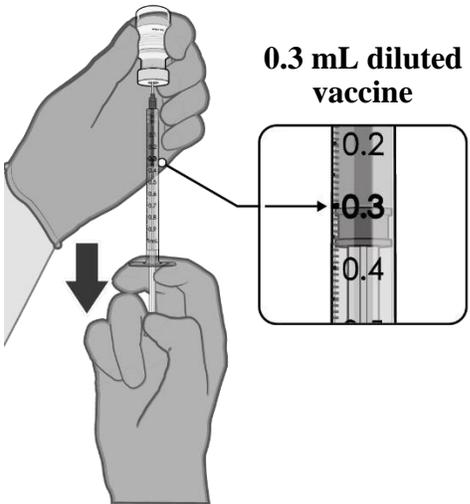
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.



**Record appropriate date and time.
Use within 6 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 6 hours, including any transportation time.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY



0.3 mL diluted vaccine

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty.

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.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- 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.
- Discard any unused vaccine within 6 hours after dilution.

Disposal

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