World Health Organization
REGIONAL OFFICE FOR Europe

Fact sheet for health workers:

Comirnaty® Pfizer/BioNTech BNT162b2 vaccine

(International nonproprietary name: tozinameran)

General information

Vaccine:	Comirnaty® (Pfizer Europe MA EEIG, Belgium)
Vaccine platform:	mRNA vaccine
Vaccine characteristics:	Non-live vaccine, mRNA formulated with lipid nanoparticles, allowing uptake into cell cytosol; mRNA degrades rapidly and does not enter cell nucleus

Age indication:	16 years of age and older
Dosage:	2 doses, 21-28 days apart
Route and site of administration:	Intramuscular in the deltoid muscle of the upper arm

WHO recommendation for Emergency Use Listing: 31 December 2020

Vaccine schedule

Two doses given with an interval of 21–28 days between doses. Countries facing vaccine supply constraints combined with high disease burden may exceptionally extend the interval between doses up to 42 days. A series started with Comirnaty® should be completed with this product.

Vaccine efficacy (VE)

- The vaccine was highly efficacious against laboratory-confirmed COVID-19 from seven days after the second dose and until the end of the follow-up period.
- VE was high in subgroups at higher risk of severe COVID-19, including people >65 years of age, with comorbidities* or obesity.

VE in participants after having received full series of vaccination (2 doses)	
Overall (including participants with/ without evidence of prior SARS-CoV-2 infection)	94.6% VE (95% CI: 89.9–97.3%) regardless of sex, race or ethnic group of vaccine recipients (9 cases in vaccinated group, 169 cases in placebo group) 95.0% VE (95% CI: 90.3–97.6%) if limited to participants without previous SARS-CoV-2 infection
By age groups: individuals aged ≥16-64 years individuals aged ≥65 years individuals aged ≥75 years	 95.1% VE (95% CI: 89.6–98.1%) 94.7% VE (95% CI: 66.7–99.9%) 100% VE (95% CI: 13.1–100%)
With any comorbidity* or obesity	95.3% VE (94.7% VE in those with no comorbidity) ***Note: these analyses were not adequately powered.***

CI = confidence interval.

* Comorbidities studied include hypertension; diabetes; asthma; pulmonary, liver or kidney disease; chronic HIV; hepatitis B or C infection (stable and controlled).

Vaccine safety

- The most common solicited adverse reactions included injection site pain, fatigue, headache, myalgia, chills, arthralgia, fever/pyrexia, injection site redness and swelling, nausea, malaise and lymphadenopathy.
- Adverse reactions were mostly mild, moderate and short lived (median duration: 1–2 days).
- Adverse reactions were generally milder and less frequent in the older age group (>55 years) compared to the younger age group (16–55 years).
- Adverse reactions tend to increase after the second dose.
- Adverse events that would potentially require longer follow-up include lymphadenopathy, Bell's palsy (acute peripheral facial paralysis) and allergic reactions.

Contraindications and precautions

Contraindications:

- History of severe allergic reaction (e.g. anaphylaxis) to any vaccine component, especially known history of severe allergic reaction to polyethylene glycol or related molecules

Precautions:

- Allergic reaction to any other vaccine or injectable therapy
- Acute febrile illness
- Individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following intramuscular administration

Special conditions and groups

Condition/group	SAGE recommendation
Pregnancy	• Vaccination is not recommended unless the benefit of vaccinating a pregnant woman outweighs the risks (e.g. health workers at high risk of exposure).
Breastfeeding	• Vaccination should be offered if a lactating woman is part of a group recommended for vaccination (e.g. health workers). • Discontinuation of breastfeeding after vaccination is not recommended.
Immunocompromised persons	• Vaccination may be offered if an immunocompromised person is part of a group recommended for vaccination. • Immune response may be reduced.
Persons with autoimmune condition	• Vaccination may be offered to persons with autoimmune condition who have no contraindication for vaccination.
Persons with history of Bell's palsy	• Vaccination may be offered to persons with a history of Bell's palsy who have no contraindication for vaccination.
Persons with food (incl. eggs, gelatin), contact (incl. latex) or seasonal allergies	• Food, contact or seasonal allergies are not considered a precaution. • Vial stoppers are not made with natural rubber latex; the vaccine does not contain eggs or gelatin.
Persons >85 years of age and very frail older persons	• These particular groups of people were not included in the trial. • Safety and immunogenicity data obtained in a large subset of older persons with/without comorbidities suggest that the benefits of vaccination outweigh potentials risks in these particular groups.
Children, adolescents <16 years of age	• Vaccination in individuals <16 years old is not recommended.
Persons with current acute COVID-19	• Vaccination should be deferred until the person has recovered and the criteria for discontinuation of isolation are met.
Persons who have previously had SARS-CoV-2 infection	• Vaccination may be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. • Persons with PCR confirmed SARS-CoV-2 infection in the preceding 6 months may delay vaccination until near the end of this period.
Persons who previously received passive antibody therapy as part of a COVID-19 treatment	• Vaccination should be deferred for at least 90 days.

PCR = polymerase chain reaction;
SAGE = Strategic Advisory Group of Experts on Immunization.

Sources:

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5. 5. Pfizer-BioNTech COVID-19 Vaccine. In: Vaccines & Immunizations [website]. Atlanta: Centres for Disease Control and Prevention; 2021 https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html , accessed 2 February 2021).

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