Schweizerische Eidgenossenschaft
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Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Public Health Directorate

COVID-19 vaccine profiles

These profiles do not replace the technical information on the vaccines. For further information, medical personnel should consult the manufacturer's technical information authorised by Swissmedic.

Status on 10 January 2021

Further information on the vaccines will follow. These profiles will be augmented and updated on an ongoing basis.

Vaccine / Properties	Comirnaty®	COVID-19 vaccine Moderna®
Technical designation	BNT162b2	mRNA-1273
Product licence holder	Pfizer/BioNTech, USA/Germany	Moderna, USA
Vaccine type	mRNA vaccine	
Antigen composition	SARS-CoV-2 spike protein	
Adjuvant	None. The mRNA is enclosed in lipid particles.	
Potentially allergenic additives	In particular polyethylene glycol (PEG or macrogol)	
Approved indication	Active immunisation to protect from COVID-19 caused by the SARS-CoV-2 virus	
	From age 16	From age 18
Dosage	2 doses of vaccine by intramuscular injection	
	Interval of at least 21 days[1]	Interval of at least 28 days[1]
Efficacy	Protects from symptomatic COVID-19 infection after 2 doses of vaccine	
	In people age 16 and over: 95% (95% CI 90-98%)[2]	In people age 18 and over: 94% (95% CI 89-97%)[2]
Adverse vaccination reactions	Pain at injection site >80% Fatigue, headache, muscle/joint pain, fever, shivering, swelling at the injection site: 10-60% – These reactions are in most cases mild to moderate and short-lived (a few days). – Older people tended to report fewer and less severe adverse vaccination reactions. – According to the available data severe, vaccine-related adverse vaccination reactions are very rare, but cannot currently be ruled out. – Cases of fascial nerve palsy have been observed in temporal relation to the vaccination. However, a causal relationship is	

[1] In accordance with the technical information from the respective licence holder, Pfizer or Moderna.
[2] The duration of efficacy is being investigated; this information will be available in the course of time.

	currently not assumed.	
	– A small number of people with a known allergic predisposition experienced a strong allergic reaction immediately after vaccination with Comirnaty®.	
Contraindications	Known severe oversensitivity to ingredients of the vaccine	
Current state of knowledge relating to specific groups		
Pregnant women/female fertility	So far little data has been available. In animal experiments, however, no negative consequences were ascertained in terms of pregnancy, embryonic/foetal development, birth or postnatal development. Likewise, no vaccine-related effects on female fertility were ascertained. Administration of a vaccination should only be considered during pregnancy if the potential benefits outweigh the possible risks to the mother and the foetus.	
Children and young adults	Under age 16: so far only little data has been available.	Under age 18: so far only little data has been available.
People with immune deficiency	This group was not investigated in the course of the trials. Vaccinal protection may be limited for these people.	
People over age 65 and people with chronic diseases	The trials included these target groups. Further information on this is available in the vaccination recommendations (in German, French or Italian).	
Mode of action of mRNA vaccines	– The vaccine contains lab-produced messenger RNA (mRNA) with the code for the SARS-CoV-2 virus's spike protein. After vaccination, some cells produce the viral spike protein (antigen). This provokes the immune system into an immune response against SARS-CoV-2 (antibodies and cellular defences). – The mRNA remains in the cytoplasm, is not transported into the cell nucleus, and accordingly cannot affect the human genetic material. – The mRNA and the proteins produced are quickly broken down again. – Only this one virus protein, but not the entire virus, can be made from this mRNA. – Several years of experience has been gained with this vaccine technology in research and development.	
Advantage of mRNA vaccines	– Given the short biological half-life of mRNA, it cannot remain permanently in the cells. – Technically straightforward and flexible production and adaptation, rapid manufacture and availability.	
Challenge involved in mRNA vaccines	– Complex logistics involved because vaccines must in some cases be stored at very low temperatures. The varying storage requirements are a function of the composition of the excipients.	

Preparation and use		
Vaccine doses per vial and preparation	– 5 doses of 0.3 ml per multi-dose vial[3] – Reconstitution with sodium chloride necessary. See Pfizer/BioNTech (in German, French or Italian) and BBraun (in German, French or Italian).	– 10 doses of 0.5 ml in a multi-dose vial; no reconstitution necessary after thawing.
Transport and storage	– Unreconstituted vials stored at < -60°C, can be stored for 5 days in the refrigerator (2-8°C); to be kept for a maximum of 2 hours at room temperature. – Once diluted at 2-25°C to be used within 6 hours.	– Vials stored at a-20°C, can be stored for 30 days in the refrigerator. At 8-25°C: unopened 12 hours, opened 6 hours.
	– The vaccines must not be shaken; instead they should only be inverted several times. – Vaccine that is not used must be disposed of after the use period has expired. – Do not pool the contents of opened vials. Further information: See Moderna, Pfizer/BioNTech (in German, French or Italian), BBraun (in German, French or Italian) and vaccination recommendations (in German, French or Italian).	

[3] recommended number of doses per vial 5; 6 doses also possible with appropriate equipment and experience. See Swissmedic.

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Links

FOPH vaccination recommendations: www.bag.admin.ch (in German, French or Italian)

Infovac: www.infovac.ch (in German, French or Italian)

Swissmedic: www.swissmedic.ch

Technical information on Comirnaty®: www.swissmedicinfo.ch (in German, French or Italian)

Technical information on COVID-19 vaccine Moderna®: www.swissmedicinfo.ch (in German, French or Italian)

Patient information for Comirnaty®: www.swissmedicinfo.ch (in German, French or Italian)

Patient information for COVID-19 vaccine Moderna®: www.swissmedicinfo.ch (in German, French or Italian)

Robert Koch Institut (German only): www.rki.de

Paul-Ehrlich-Institut: www.pei.de

Studies and trials

1. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. The New England Journal of Medicine 2020. 10.1056/NEJMoa2034577.

2. Mulligan MJ (2020) Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults. Nature(586(7830)):589-93.

3. Walsh EE, Frenck RW, JR, Falsey AR et al. (2020) Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. N Engl J Med:Epub 2020 Oct 14. https://doi.org/10.1056/NEJMoa2027906

4. Şahin U, Muik A, Derhovanessian E et al. (2020) COVID-19 vaccine BNT162b1 elicits human antibody and T H 1 T cell responses. Nature:594–599. https://doi.org/10.1038/s41586-020-2814-7

5. Anderson EJ, Rouphael NG, Widge AT et al. (2020) Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. N Engl J Med 383:2427–2438. https://doi.org/10.1056/NEJMoa2028436

6. Widge AT, Rouphael NG, Jackson LA et al. (2020) Durability of Responses after SARS-CoV-2 mRNA-1273 Vaccination. N Engl J Med. https://doi.org/10.1056/NEJMc2032195

7. Baden LR, El Sahly HM, Essink B et al. (2020) Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. New England Journal of Medicine. https://doi.org/10.1056/NEJMoa2035389

8. Jackson LA, Anderson EJ, Rouphael NG et al. (2020) An mRNA Vaccine against SARS-CoV-2 - Preliminary Report. N Engl J Med 383:1920–1931. https://doi.org/10.1056/NEJMoa2022483