COVID-19 mRNA vaccine profiles

These profiles do not replace the technical information on the vaccines and the recommendation of vaccination. For further information, medical personnel should consult the manufacturer’s technical information authorised by Swissmedic as well as the recommendation of vaccination of FOPH and FCV.

Status on 30.11.2021
Further information on the vaccines will follow. These profiles will be augmented and updated on an ongoing basis. (Amendments are highlighted in yellow.)

<table>
<thead>
<tr>
<th>Properties</th>
<th>Vaccine</th>
<th>Comirnaty®</th>
<th>Spikevax®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical designation</td>
<td>BNT162b2</td>
<td>mRNA-1273</td>
<td></td>
</tr>
<tr>
<td>Product licence holder</td>
<td>Pfizer/BioNTech, USA/Germany</td>
<td>Moderna, USA</td>
<td></td>
</tr>
<tr>
<td>Vaccine type</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
<td></td>
</tr>
<tr>
<td>Antigen composition</td>
<td>SARS-CoV-2 spike protein</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Adjuvant</td>
<td>None. The mRNA is enclosed in lipid particles.</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Potentially allergenic additives</td>
<td>In particular polyethylene glycol (PEG or macrogol)</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Approved indication</td>
<td>Active immunisation to protect from COVID-19 caused by the SARS-CoV-2 virus</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>From age 12</td>
<td>From age 12</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Dosage for basic immunisation</td>
<td>2 doses of vaccine by intramuscular injection¹</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Interval of at least 21 days²</td>
<td>Interval of at least 28 days²</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Protects from symptomatic COVID-19 infection after 2 doses of vaccine³</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>In people age 16 and over:</td>
<td>95% (95% CI 90-98%)</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Adolescents aged 12-15 years</td>
<td>100 % (95 % CI 75-100 %)</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>In people age 18 and over:</td>
<td>94% (95 % CI 89-97 %)</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
<tr>
<td>Adolescents aged 12-17 years</td>
<td>100 % (95 % CI 29 - NE %)</td>
<td>mRNA vaccine</td>
<td>mRNA vaccine</td>
</tr>
</tbody>
</table>

¹ For possible exceptions to this vaccination schedule (especially in case confirmed SARS-CoV-2 infection or severe immunodeficiency), see the vaccination recommendations (chapter 2.1.1 and 3.3).
² In accordance with the technical information from the respective licence holder, Pfizer or Moderna.
³ Efficacy against the SARS-CoV-2 variants circulating in 2020; efficacy against severe disease by the delta variant is maintained but reduced for mild disease. The latest data show a slight to moderate decrease in protection against severe illness from 6 months after basic immunisation in people aged 65 years and over, although no significant decrease has so far been observed for Spikevax® in this age group. According to current knowledge, the approved mRNA vaccines also guarantee good protection for at least 12 months against severe illness in people aged <65 years.
### Adverse vaccination reactions

**Very frequent adverse vaccination reactions for both vaccines (>10%)**:

- Pain at injection site: >80%
- Fatigue: > 60%
- Headache: > 50%
- Muscle/joint pain, shivering: 20-60%
- Fever, swelling at the injection site: ca.10%

In addition very frequent (>10%) with Spikevax®:

- Nausea/vomiting: 20%
- Lymphadenopathy: 20%
- Redness at the injection site: 10%

- 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.
- Adolescents and young adults tended to report more frequently about AVRs.
- A small number of people experienced a strong allergic reaction immediately after vaccination.
- In very rare cases, myocarditis and pericarditis have been reported after vaccination, which were mild in most cases. This particularly concerns Spikevax®. The cases occurred primarily within 14 days of vaccination, and more frequently after the second dose and in younger men.
- At this moment, the risk of rare extraordinary or serious side-effects can currently not be ruled out. Such side-effects occur within months of the vaccination. However, the risk is very low according to current knowledge.
- The expected side-effects after the booster are comparable with those after the second vaccine dose.

### Contraindications

Known severe allergic reactions (e.g. anaphylaxis) to a vaccine component or after receiving a previous dose.

- These may be relative or absolute contraindications.

According to the vaccination recommendation, it is advisable to seek advice from a doctor specialised in allergology and clinical immunology.

For further specifications of relative and absolute contraindications due to allergic and non-allergic reactions before vaccination or after the first dose, see Vaccination recommendation for mRNA vaccines Section 2.3.1, Section 9.5 and Annex 2 (in German and French only).

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4 An infection with SARS-CoV-2 can also cause myocarditis. According to current knowledge, the risk of developing myocarditis after a COVID-19 infection is many times higher than after an mRNA vaccination.
<table>
<thead>
<tr>
<th>Pregnant women/female fertility</th>
<th>Pregnant women have a significantly higher risk of experiencing serious illness after becoming infected with COVID-19, in particular as regards stays in the intensive care unit, intubation and ventilation and an increased risk of mortality (Chinn J., 2021; Villar J., 2021). The risk of premature birth (with the possible consequences for the newborn baby) is also considerably higher. The increasing evidence on the safety and efficacy of COVID-19 vaccination with an mRNA vaccine during pregnancy confirms that the benefits of vaccination significantly outweigh the risks. (CDC Pregnancy Registry: Public Health England; Shanes ED, 2021; Theiler RN, 2021; Trostle ME, 2021). This evidence is growing steadily and will continue to be monitored closely. Vaccination (basic immunisation or booster vaccination, depending on the situation) is therefore recommended from the 2nd trimester. Vaccination with an mRNA vaccine is also recommended for breastfeeding women.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children under 12 years</td>
<td>Under age 12: so far only little data has been available and vaccination is not recommended for this age group so far.</td>
</tr>
<tr>
<td>Booster</td>
<td><strong>Comirnaty®</strong>: authorised for people who are at especially high risk aged 12 years or over, and all other people aged 16 years or over, at least 6 months after the second vaccine dose. &lt;br&gt;<strong>Spikevax®</strong>: authorised for people who are at especially high risk aged 12 years or over, and all other people aged 18 years or over, at least 6 months after the second vaccine dose. A booster is recommended from at least 6 months after complete basic immunisation (i.e. 2 vaccine doses spaced 28 days apart or one vaccine dose in combination with a confirmed COVID infection at least 4 weeks apart). If a confirmed SARS-CoV-2 infection occurs within 6 months of completion of the basic immunisation, a booster vaccination is recommended 6 months after this infection. Cave: A confirmed infection &gt; 6 months after basic immunisation is considered a booster and no booster vaccination is necessary. This recommendation applies in principle for <strong>everyone aged 16 years or over, in particular</strong>&lt;br&gt;– all people aged ≥65 years&lt;br&gt;– residents of and those cared for in retirement homes, care homes and day care facilities for the elderly. For further details, see the mRNA vaccines supplement on booster vaccination (available in German or French).</td>
</tr>
<tr>
<td>Mode of action of mRNA vaccines</td>
<td>– 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).&lt;br&gt;– The mRNA remains in the cytoplasm, is not transported into the cell nucleus, and accordingly cannot affect the human genetic material.&lt;br&gt;– The mRNA and the proteins produced are quickly broken down again.&lt;br&gt;– Only this one virus protein, but not the entire virus, can be made from this mRNA.&lt;br&gt;– Several years of experience has been gained with this vaccine technology in research and development.</td>
</tr>
</tbody>
</table>

5 For application in pregnancy, see the vaccination recommendations available in German or French.
### 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
- 6 doses of 0.3 ml (30 µg per dose for basic immunisation as well as for booster vaccination) per multi-dose vial\(^6\)
- Reconstitution with sodium chloride necessary. See Pfizer/BioNTech (in [German](https://www.pfizer.com/), [French](https://www.pfizer.com/), or [Italian](https://www.pfizer.com/)) and BBraun (in [German](https://www.bbraun.com/), [French](https://www.bbraun.com/), or [Italian](https://www.bbraun.com/)).

#### Transport and storage
- Unreconstituted vials stored frozen for 9 months at -90°C to -60°C (during this period storage once for 2 weeks at -25°C to -15°C), thawed 1 month in the refrigerator (2-8°C); to be kept for a maximum of 2 hours at room temperature.
- Once opened/diluted at 2-30°C to be used within 6 hours.

#### Further information
- 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](https://www.moderna.com/), Pfizer/BioNTech (in [German](https://www.pfizer.com/), [French](https://www.pfizer.com/), or [Italian](https://www.pfizer.com/)), BBraun (in [German](https://www.bbraun.com/), [French](https://www.bbraun.com/), or [Italian](https://www.bbraun.com/)) and [vaccination recommendations](https://www.swissmedic.ch) (available in [German](https://www.swissmedic.ch) or [French](https://www.swissmedic.ch)).

\(^6\) recommended number of doses per vial 5; 6 doses also possible with appropriate equipment and experience. See [Swissmedic](https://www.swissmedic.ch).
Links

FOPH vaccination recommendations: www.bag.admin.ch (available in [German](https://www.bag.admin.ch) or [French](https://www.bag.admin.ch))

Infovac: www.infovac.ch (in [German](https://www.infovac.ch), [French](https://www.infovac.ch) or [Italian](https://www.infovac.ch))

Swissmedic: [www.swissmedic.ch](https://www.swissmedic.ch)

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

Technical information on Spikevax®: www.swissmedicinfo.ch (in [German](https://www.swissmedicinfo.ch), [French](https://www.swissmedicinfo.ch) or [Italian](https://www.swissmedicinfo.ch))

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

Patient information for Spikevax®: www.swissmedicinfo.ch (in [German](https://www.swissmedicinfo.ch), [French](https://www.swissmedicinfo.ch) or [Italian](https://www.swissmedicinfo.ch))

Robert Koch Institut (German only): [www.rki.de](https://www.rki.de)

Paul-Ehrlich-Institut: [www.pei.de](https://www.pei.de)