



Fact sheet: COVID-19 vaccination with mRNA vaccines

Why does vaccination for COVID-19 make sense?

- In most cases, the progression of an infection with SARS-CoV-2 is mild and without complications. However, *older people*, and *people with chronic diseases* in particular are at a significantly higher risk of suffering a severe case of the disease with complications, like admissions to hospital and deaths.
- *Younger people without chronic diseases* can also suffer severe cases with complications, albeit much more rarely than older people.
- An infection can result in *health impairments that last for a long time, even for younger people*.
- There is a risk that health care will be overloaded due to the large number of severe cases of the disease, meaning that care can no longer be fully guaranteed for members of the public.
- Measures to manage the SARS-CoV-2 pandemic are *severely restricting the social and economic life of individuals and the whole community*. The fewer people contract the disease, the more quickly *everyday life can return to normal*.
- The mRNA vaccine technologies available in the first phase have been undergoing testing for years and are now moving to clinical use. mRNA vaccines have demonstrated a very good efficacy and safety profile in clinical and observational studies. Vaccination is much safer for individuals than an infection and its potentially severe consequences.
- This leads to a major reduction in the number of severe cases and deaths, and thus to a reduction in *admissions to hospital*
- Current data indicate that transmission of the virus can be significantly reduced by full vaccination

Target groups

According to the vaccination strategy and vaccination recommendations formulated by the Federal Vaccination Commission (EKIF/CFV) and the Federal Office of Public Health (FOPH/BAG), vaccination against Covid-19 is recommended for all adults (from age 16). This recommendation applies in particular to persons at increased risk of severe disease (vulnerable persons, VP) and their close contacts. Vaccination is also recommended for adolescents aged 12-15 years, especially those with chronic diseases¹ According to the vaccination strategy, the following target groups have been defined:

1. Vulnerable persons (VP):

People aged 65 and over, as well as adults under 65 with chronic diseases (from the age of 16). These include specific forms² of

- Arterial hypertension
- Cardiovascular diseases
- Diabetes mellitus
- Lung and respiratory diseases (including COPD and pulmonary fibrosis)
- Congenital or acquired immunodeficiency and immunosuppressive therapy (including cancers)³
- Cancer
- Obesity (BMI ≥ 35 kg/m²)
- Renal insufficiency
- Liver cirrhosis

furthermore people from the age of 16 years with Trisomy 21.

2. **Personnel with patient contact and personnel caring for VP**
3. **Close contacts of VP (household members or caring family members from the age of 16 years), in particular persons with immunodeficiency**
4. **People aged 16 to 64 in community facilities with an elevated risk of infection and outbreak**
5. **All other people aged 16 to 64 years**
6. **Young people between 12-15 years**

For children under 12 years of age⁴: There are no data available for the use of the vaccine in this age group. Therefore, vaccination is not yet recommended.

The vaccine is recommended⁵ for all pregnant women from the second trimester, especially to women with certain types of chronic diseases². Women who are planning to become pregnant should also be vaccinated against COVID-19. Vaccination is also possible in principle in the 1st trimester and can be carried out at the request of the pregnant woman. Vaccination with an mRNA vaccine is also recommended for breastfeeding mothers. The increasing evidence on the safety and efficacy of COVID-19 vaccination with an mRNA vaccine during pregnancy confirms that the benefits of vaccination outweigh the risks. No written consent or medical certificate is required.

Contraindications and indications after clarification of a reservation

Possible contraindications, which must be assessed by a medical specialist, are:

- Anaphylaxis or general allergic reaction to vaccine ingredients, known or probable immediate-type sensitisation to polyethylene glycol (PEG), tromethamine (trometamol, TRIS)⁴, severe anaphylaxis (grade III/IV) with unclear or unresolved trigger, idiopathic anaphylaxis as well as anaphylaxis after the first dose of vaccine. In the latter case, the vaccination series can be completed with the Janssen-Cilag vector vaccine after a consultation with a specialist in allergology and clinical immunology.
- Myocarditis/pericarditis after 1st vaccination dose: until additional safety data are available, it is generally recommended to postpone the 2nd dose. However, the 2nd dose may be considered after consultation with a specialist and with a personal risk-benefit analysis.

For further specification of relative or absolute contraindications of allergic or non-allergic nature, see the vaccination recommendation for mRNA vaccines chapter 2.3.1, chapter 9.5 and appendix 2⁵.

For people with immunodeficiency: These people are at a higher risk of severe cases of the disease and can be vaccinated in accordance with the vaccination recommendations and following a careful assessment of the benefits and risks by the attending specialist. The efficacy for these people might possibly be reduced (see vaccination scheme). You will find more specific information on precautionary measures and vaccinating people with immunodeficiency and with known acute severe allergies in the vaccination recommendation⁵.

For pregnant women in the 1st trimester: The vaccination can be carried out at the woman's request.

¹ Capacity to consent: For adolescents aged 12 years and over who consult without a legal representative, the capacity to consent must be assessed on an individual basis.
² [Categories of persons at high risk](#) and here www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - English documents

³ Here the indication for vaccination must be assessed by the attending specialist, carefully weighing up the risks and benefits.

⁴ www.swissmedicinfo.ch (in German, French)

⁵ www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen (only available in [german](#) and [french](#).)

Vaccines⁴

The mRNA vaccines are so-called messenger ribonucleic acid (mRNA) vaccines manufactured by Pfizer/BioNTech and Moderna. This type of vaccine has been in testing in research for ten years already.

The vaccines contain lab-produced messenger RNA (mRNA)⁶ with the information 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 involving the formation of antibodies and cellular defences against SARS-CoV-2. 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.

Efficacy

According to clinical trials and observational studies, the mRNA vaccines offer a very high degree of protection from COVID-19 for adults of around 94% (95% CI 89%-98%) (variants of 2020 and Alpha), and also from severe cases (all known variants incl. Delta). Very good protection has also been demonstrated for older people. For young people aged 12-15 years, the protective effect was also very high (100%, 95 CI 29-100%). The latest data show a slight decrease in protection against severe illness from 6 months after basic immunisation in people aged 65 years and over; the efficacy of Spikevax® in this age group was greater than that of Comirnaty®. According to current knowledge, the approved mRNA vaccines guarantee good protection for at least 12 months against severe illness in people aged under 65 years, regardless of the currently known virus variants. New evidence in this regard will be closely monitored. Data on asymptomatic infections indicate that transmission of the virus to others is significantly reduced after full vaccination. Data from vaccinated persons infected with SARS-CoV-2 Delta suggest a less good reduction in viral transmission compared with infection with SARS-CoV-2 Alpha. But compared to unvaccinated individuals, vaccination still effectively prevents infection and appears to shorten the infectious phase in infected individuals, and thus may continue to reduce transmissions even with the Delta variant.

Known side-effects

According to the results of the clinical trials, the vaccines are well tolerated. However, they can be associated with mild to moderate side effects that disappear within a few days. The side effect profile of adolescents aged 12-15 years is similar to that in young adults, according to currently available data. The most common side-effects are the kind of local reactions that also occur with other vaccinations. The most frequent side-effect⁷ include pain at the injection site (> 80%), fatigue (> 60%) and headache (> 50%). Chills, aching muscles and joints (20%–60%), and fever and swelling at the injection site (around 10%) may also occur. In the Spikevax® (Moderna), there have also been very frequent reports of nausea/vomiting (>20%), lymphadenopathy (20-40%) and redness at the injection site (10-30%). According to reports, increased side effects were observed following the second vaccine dose. Older people display fewer side-effects. Delayed local inoffensive reactions were observed around one week after the vaccination and usually manifest themselves as a well-defined area of red, swollen skin on the injected arm, in some cases accompanied by pain and/or itching ("COVID Arm"). These reactions improve without further measures after a few days. Such an event is not a contraindication to a second vaccine dose.

Severe allergic reactions to a vaccine ingredient (in particular PEG) are very rare and mostly occur immediately after the vaccination. The first signs of a severe reaction, such as shortness of breath, drop in blood pressure or severe reactions at the injection site mostly occur within minutes. The risk of rare extraordinary or serious side-effects cannot currently be ruled out. Such side-effects occur within months of the vaccination. However, experience shows that the risk of this is very low. The institutions in charge observe possible signs closely. Other health problems may continue to arise, sometimes also in direct temporal relation to a vaccination. This does not mean, however, that this is necessarily a result of the vaccination.

Very rare cases of myocarditis and pericarditis have been reported. The cases occurred mainly within two weeks of vaccination, more frequently after the second vaccination, more often in younger men and were mostly of mild severity.

The risk of other severe side-effect from the vaccination is according to the actual evidence much smaller than the risk of a complication of COVID-19, the disease from which the vaccination protects.

A doctor, pharmacist or vaccination centre should be notified of any serious and unexpected side-effects. These notifications are recorded in Swissmedic's vigilance system⁸. If necessary action will be taken on this basis.

Vaccination regimen

Basic immunisation

Basic immunisation comprises 2 injections into the deltoid muscle at an interval of 28 days or one vaccine dose in combination with a confirmed COVID infection at an interval of at least 4 weeks. Both vaccinations should be with the same vaccine. The anticipated vaccinal immune protection occurs around 1–2 weeks after basic immunisation.

Note:

Basic immunisation is considered complete (i) after the second vaccine dose, (ii) after one vaccine dose following confirmed SARS-CoV-2 infection (PCR/antigen test/anti-spike or anti-nucleocapsid IgG⁹ or (iii) after confirmed SARS-CoV-2 infection (PCR/antigen test or anti-nucleocapsid IgG) after the first vaccine dose. In principle a minimum interval of 4 weeks applies (exception: anti-nucleocapsid IgG after first injection: no minimum interval necessary).

As vaccination after infection can increase protection effectively, particularly against new variants, vaccination within 3 months of infection is recommended. However, there is no upper time limit for vaccination with one dose after infection.

Persons with severe immunodeficiency are an exception and should receive 2 vaccine doses, even in the case of a confirmed infection.

For persons with severe immunodeficiency (e.g. with severe immunosuppressive treatments in transplantation, autoimmune diseases or malignant neoplasms) a 3rd dose is recommended from 4 weeks after the 2nd dose for basic immunisation. The ideal time for administering the 3rd dose should be discussed with the attending specialist (see chapter 3.3. recommendation of vaccination)

Serological testing is not generally recommended and should not be performed explicitly to determine the vaccination schedule. Serological testing is recommended following basic immunisation (third dose) for persons with severe immunodeficiency (vaccination recommendation, section 3.3).

Booster:

A booster is recommended for people aged 65 years and over and residents and those cared for in care facilities for the elderly from 6 months after complete basic immunisation. If a confirmed SARS-CoV-2 infection occurs within 6 months after completion of the basic immunisation, a booster vaccination is recommended 6 months after this infection. The booster should be with the same vaccine where possible. Caution: A confirmed infection > 6 months after basic immunisation is considered a booster and no booster vaccination is necessary.

In the case of Spikevax®, the booster is recommended at a reduced dose of 50 µg. In individual cases, a booster can be recommended for vulnerable persons aged 16-64 years with chronic illnesses with the highest risk¹⁰ following an individual medical risk-benefit analysis with the attending physician. To date, no decrease in protection against severe illness has been observed in these individuals.

Caution: no more than 3 vaccine doses in total are currently recommended. The vaccination should be postponed in the event of acute febrile illness.

Care after the vaccination

Given that all vaccinations entail the risk of allergic reaction, a doctor or qualified pharmacist should be available to be brought in if required. The necessary precautions to treat an anaphylactic reaction must be taken. The person vaccinated should remain on site for at least 15 minutes after the vaccination and be instructed in possible adverse vaccination events

⁶ mRNA is basically also produced by the human body itself, and serves as a readable template for the production of endogenous proteins. Afterwards the mRNA is broken down again. The vaccine provides another template of this sort which is then broken down again via the normal processes.

⁷ www.swissmedicinfo.ch

⁸ www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/

[market-surveillance/pharmacovigilance/elvis.html](https://www.bag.admin.ch/press-releases/press-releases-detail/62076)

⁹ [Statements and consequences of SARS-CoV-2 tests](https://www.bag.admin.ch/press-releases/press-releases-detail/62076) and on: www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - English documents

¹⁰ Disease definitions according to [Table 2](#) of the Recommendations for mRNA vaccines and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - English documents



and the procedure if they occur. This especially applies when people with known severe allergic reactions are vaccinated. If the first vaccination went without a problem, the observation time after the second vaccination can be reduced to 5 minutes.

Vaccinated persons should be advised to watch for signs of myocarditis and pericarditis, such as shortness of breath, palpitations and chest pain, and to seek medical attention immediately if such signs appear.

The generally recommended hygiene and behavioural measures (masks, distancing, hand hygiene) must continue to be observed before, during and also after the vaccination, with the exception of private meetings between fully vaccinated persons (waiver of mask and distance possible) as well as events with a certificate (according to the organiser's instructions). There is no minimal interval to other vaccinations.

Availability of vaccine

Responsibility for organising vaccinations for COVID-19 lies with the cantonal departments of health. They will provide information on how and where people can be vaccinated. The vaccination is free of charge.

You will find further information at

- www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen
- www.infovac.ch
- www.foph-coronavirus.ch/vaccination

