



Fact sheet: COVID-19 vaccination with Comirnaty® for children aged 5 to 11

Why can vaccination against COVID-19 make sense?

- In most cases, in this age group the progression of an infection with Sars-CoV-2 is mild and without complications. But in very rare cases, in children of this age, complications (PIMS: paediatric multisystem inflammatory syndrome) and hospitalisations can also occur.
- An infection may potentially result in health impairments that last for a long time ("long COVID"), in rare cases for younger people too.
- For children whose health is already severely impaired by chronic illness, additional illness/infection should be prevented as far as possible.
- For children with close contacts (household members) to people who cannot get protection with the vaccination, for example because of immunodeficiency, the vaccine is recommended because current data indicate that transmission of the virus can be reduced for a certain period of time after full vaccination.
- Vaccination can help reduce the negative indirect impact of individual and collective measures (e.g. isolation and quarantine) and avoid the consequences of frequent exposure (e.g. at school or in free time).
- The available mRNA vaccine technologies have been tested for years and have already been administered to billions of people. Comirnaty® from Pfizer/BioNTech displayed a very good efficacy and safety profile in clinical trials. A children's formulation of the vaccine has been investigated; it gives vaccine protection of 90% and is well tolerated. The vaccination has been authorised by Swissmedic and is deemed to be safe.

Target groups

According to the vaccination recommendations drawn up by the Federal Vaccination Commission (EKIF) and the Federal Office of Public Health (FOPH), vaccination against COVID-19 is recommended for all children aged 5 to 11 whose parents/guardians wish to have this vaccination for their child after an individual assessment of the benefits and risks.

This particularly applies to children aged 5 to 11 who

- a) are already severely impaired because of a chronic illness, in order to if possible prevent any additional illness/infection.
- b) are close contacts (household members) of people who cannot themselves be protected by vaccination (e.g. people with immune deficiency).

The assessment of the benefits and risks should include aspects of the risk of disease, the utility and efficacy of the vaccine, and the safety and timing of the vaccination¹.

Contraindications and indications after clarification of a reservation

Possible contraindications that must be assessed by a specialist are:

- Anaphylaxis or general allergic reaction to ingredients of the vaccine², known or probable immediate-type sensitisation to polyethylene glycol (PEG), tromethamine (trometamol, TRIS), severe anaphylaxis (grade III/IV) with unclear or as yet unresolved trigger, idiopathic anaphylaxis, and anaphylaxis after the first dose of the vaccine.
- Myocarditis/pericarditis after 1st vaccination dose: until additional safety data are available, it is generally recommended to postpone the 2nd dose.

For further specification of relative or absolute contraindications of an allergic or non-allergic nature, see the vaccination recommendation on mRNA vaccines in section 2.3.1 and section 105 as well as appendix 2¹.

For children with immune deficiency: With these children, as far as possible any additional illness/infection should be avoided. They can be vaccinated in accordance with the vaccination recommendations and indication by the attending specialist. The efficacy for these children might possibly be reduced (see section on vaccination schedule). You will find more specific information on precautionary measures and vaccinating children with severe immune deficiency and with known acute severe allergies in the vaccination recommendations¹.

Vaccines²

Pfizer's mRNA vaccine is a so-called messenger ribonucleic acid (mRNA) vaccine (specific children's formulation). This type of vaccine has been in testing in research for ten years already. The vaccines contain lab-produced messenger RNA (mRNA)³ 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 reaction 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

Caution: The following information on efficacy relates to SARS-CoV-2 variants before the emergence of the Omicron variant. The efficacy of the children's vaccine against the Omicron variant is currently being investigated; it can, however, be assumed that similar to the case with adults, the protection afforded by the vaccine is reduced.

According to the authorisation trial (trial period June to October 2021), in children aged from 5 to 11 the mRNA vaccine Comirnaty® is 90.7% effective against symptomatic COVID-19 disease (95% CI 67.7 – 98.3). No severe cases of the disease occurred in the course of the trial. No data are yet available on the duration of protection and protection against transmission in this age group.

Known side-effects

According to the results of the clinical trials, the vaccines are well tolerated, but may be associated with mild to moderate side-effects that resolve within a few days. According to available data, the side effect profile in children aged 5 to 11 years is similar to that in adolescents and young adults. However, side-effects basically occur less frequently in children.

The most common side-effects are the kind of local reactions that also occur with other vaccinations. The most frequent include pain at the injection site (>80%), fatigue (>50%) and headaches (>30%)². Swelling at the injection site, muscle pain, shivering (≥10%), joint pain, fever, diarrhoea and vomiting (<10%)¹ can also occur. The side-effects were increasingly observed after the 2nd vaccination dose. **Pharmacovigilance data from the US after administration of 8.7 million doses of the Comirnaty® children's vaccine show a similar safety profile to the authorisation trial.**

Harmless, spontaneously resolving local reactions in the form of well-defined, in some cases extensive skin reddening and swelling on the vaccinated arm, sometimes with pain and/or itching ("COVID arm") have been observed rarely in adults with a delay (approximately one week after vaccination). It is not yet known whether this

¹ [Vaccination recommendation for mRNA vaccines against COVID-19](https://www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen) and on www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - COVID-19 vaccination (German, French and Italian only)

² www.swissmedicinfo.ch

³ 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.

can also occur in children. Such an occurrence is not a contraindication for a second dose of vaccine.

Severe allergic reactions to a vaccine ingredient (in particular polyethylene glycol (PEG) and tromethamine/trometamol (TRIS)) 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.

Very rare cases of myocarditis and pericarditis have been reported to date in people aged 12 and older. Cases have occurred mainly within two weeks of vaccination, more frequently after the second vaccination, more often in young males, and have been mild in most cases. **In the abovementioned pharmacovigilance study on the children's vaccine in the US, very rare cases of myocarditis were observed (a total of 11 cases in 8.7 doses of children's vaccines). A causal relationship between the vaccination and these very rare occurrences cannot be ruled out. However, this does nothing to alter the risk/benefit profile for this target group.**

The risk of other rare extraordinary or serious side-effects cannot currently be completely ruled out. Such side-effects occur within months of the vaccination. However, experience shows that the risk of this is very low. Those responsible closely observe possible signs. 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. According to experts, the potential protection afforded by vaccination outweighs the risk of a severe rare side effect due to the vaccination, which cannot yet be completely ruled out.

A doctor, pharmacist or vaccination centre should be notified of any serious or unexpected side-effects. These notifications are recorded in Swissmedic's vigilance system⁴. If necessary, action will be taken on this basis.

Vaccination schedule

Basic immunisation¹:

Basic immunisation comprises 2 injections into the deltoid muscle at an interval of 28 days. The anticipated vaccinal immune protection occurs around 1–2 weeks after the primary course.

Severely immunodeficient children (e.g. who have severe immunosuppressive treatments in transplantation, autoimmune diseases or malignant neoplasms) aged 5 to 11 receive 2 vaccine doses (or, in the case of a confirmed infection, 2 antigen exposures) for basic immunisation and a subsequent serology test. Depending on the serology test, a third dose of vaccine (off label) can be administered; cf. vaccination recommendations¹.

Note:

Without a specific recommendation, it is not recommended for recovered healthy children to be vaccinated against COVID-19 for the time being (in principle there is no contraindication for vaccination after recovery in this age group).

For those children with a specific recommendation owing to (a) a chronic disease or (b) contact with immunodeficient persons, one vaccine dose is recommended after infection. Vaccination is recommended within 3 months after infection. However, there is no upper time limit for vaccination with one dose following infection.

A confirmed SARS-CoV-2 infection is defined as follows: PCR/antigen test/anti-spike or anti-nucleocapsid IgG⁵. Basically, a minimum interval of 4 weeks applies (with the exception of anti-nucleocapsid IgG after the 1st vaccination, where no minimum interval is necessary).

In the absence of data on the vaccination of severely immunodeficient children aged 5 to 11 years, the attending specialist should decide whether a further vaccine dose is indicated in the case of a confirmed infection and one vaccine dose after a serological test¹.

As soon as data on the duration of protection in children are available, information on the need for booster vaccinations will be provided.

Care after the vaccination

Given that all vaccinations entail the risk of allergic reaction, a doctor 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 first vaccination and be instructed in possible adverse vaccination events 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 individuals should be alerted to signs of myocarditis and pericarditis, such as shortness of breath, palpitations and chest pain, and seek medical attention immediately if such symptoms occur.

The generally recommended hygiene and behavioural rules (masks, distancing and hygiene) must continue to be observed before, during and also after vaccination.

There is no need to keep to a minimum interval from 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/

⁴ www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/pharmacovigilance/elvis.html

⁵ [Statements and consequences of SARS-CoV-2 tests](#) and on: www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - English documents

