



EXPLANATORY SHEET



Vaccination against COVID-19 with the Pfizer/BioNTech mRNA vaccine for children: important information for parents and guardians

✓ You child is being vaccinated against

This information sheet is intended to supplement the vaccination discussion with a professional. Please read this information sheet carefully before the COVID-19 vaccination and discuss any questions you have with a professional at the vaccination centre.

Vaccination recommendation for children

- Only Pfizer/BioNTech's mRNA vaccine for children is recommended and authorised for vaccinating children from age 5 to 11.
- We recommend COVID-19 vaccination for children aged 5 to 11 whose parents/guardians want it for their child after an individual assessment of the risks and benefits.

This recommendation applies particularly to:

- a) Children whose health is already severely impaired because of a chronic illness, in order to if possible prevent any additional illness/infection.
- b) Children who are close contacts (household members) of people who cannot get sufficient protection with the vaccination (for example because they have a weakened immune system).

Safety and efficacy of the children's vaccine

Swissmedic, the Swiss agency for the authorisation and supervision of therapeutic products, has closely examined and approved the Pfizer/BioNTech vaccine for children. It is very effective and safe. Thousands of children have received the vaccine in the course of trials. Side effects were rather less frequent than in adolescents and adults. More than 6 million children in the United States have already been vaccinated with at least one dose. The data currently available confirm the efficacy and safety of the vaccine. New data are being collected and reviewed by experts on an ongoing basis.

Benefits of the vaccination for children

- Very good individual protection against COVID-19:
An infection with the coronavirus in children is almost always mild and without complications. But in rare cases it can lead to serious complications¹ involving hospitalisation in children of this age too.
Not only that, but in rare cases infection can lead to long-lasting health impairments (long-term effects of COVID-19) such as fatigue and shortness of breath, even in children. For children whose health is already severely impaired by chronic illness, additional infection/illness

should be prevented as far as possible. However, even if they have a chronic illness, children are not in the group of people at particularly high risk from coronavirus.

- Influence on social and mental wellbeing:
Vaccination can help reduce the negative consequences of measures such as isolation and quarantine and avoid the effects of frequent contact with people who might be infected, for example at school or in leisure time. This is of the utmost importance, especially for children.
- Temporary protection from transmission of the virus:
Current data indicate that transmission of the virus can be reduced for a certain period of time (a few months) after full vaccination. This means vaccination may make sense for children who are close contacts (household members) of people who cannot get sufficient protection with the vaccination (for example because they have a weakened immune system).
Vaccinating children in general can also do something to reduce the transmission of the virus in their immediate environment.

Risks of the vaccination for children

So far there not so much experience has been gained with the COVID-19 vaccination for children as for adults. No noticeable problems with serious side effects have been observed in trials or among the 6 million-plus children who have been vaccinated so far. However, on the basis of the available data, possible rare side effects cannot yet be ruled out with certainty. Such side effects could be expected to emerge within a few weeks or months of the vaccination. New data are being added all the time, and experts are closely monitoring the situation and adjusting the recommendations as needed.

General information on the vaccination for children

- Two vaccinations are required, administered as an injection into the upper arm. Your child should have the second injection about four weeks after the first. For children who have recovered from COVID-19, see the section below.

¹ e.g. PIMS (paediatric inflammatory multisystem syndrome), a severe inflammatory reaction from the body (cf. FAQ on *What is PIMS?*)



- Currently booster vaccinations are not recommended for children. There is still too little data on the length of time the vaccination provides protection for and on the benefits of boosters for this age group.
- The vaccine does not contain any coronaviruses and cannot trigger COVID-19. It cannot change human DNA.
- After full vaccination, the probability of your child becoming infected with the coronavirus is significantly reduced for a certain period (a few months), and thus also the risk of transmission. However, the vaccination does not provide 100% protection.
- In people with an immune deficiency (due to an illness or therapy), the vaccination may be less effective. If your child has a weakened immune system, please seek advice from your specialist doctor.

What side effects can the vaccine have?

- If the vaccine does have side effects, these will normally be mild to moderate and only last a few days. As with other vaccinations, these are generally reactions at the injection site (especially pain, or also redness or swelling) or general symptoms (such as tiredness, headaches, muscle and joint pains, high temperature, diarrhoea, vomiting). Severe allergic reactions to a component of the vaccine (such as polyethylene glycol (PEG) or tromethamine (TRIS)) are very rare and generally occur a few minutes after the vaccination. Initial signs include shortness of breath, a drop in blood pressure or severe reactions at the injection site. Serious allergic reactions of this kind are generally easy to treat.

Recommendation: After the first injection, stay at the vaccination centre with your child for at least 15 minutes.

- In very rare cases, predominantly among young men, inflammation of the heart muscle or the pericardium has been observed shortly after vaccination. The vast majority of these cases were mild and could be treated effectively. Typical symptoms are chest pain, shortness of breath and palpitations. It is still not clear whether this risk also exists for children from 5 to 11. So far there has been too little data available for this age group, but more data is being added all the time. Among adolescents and adults, inflammation of the heart muscle or pericardium occurs much more frequently after infection with the coronavirus than after vaccination with the Pfizer/BioNTech vaccine.
- The risk of other rare serious or unexpected side effects cannot currently be ruled out.
- Experience acquired with other vaccines has shown that such events would be expected to occur within months of the vaccination. According to current research, the risk of this happening is, however, very low. The responsible agencies are closely monitoring possible indications.

So far, no other noticeable problems have been found in the vaccination trials that are ongoing with thousands of children, or in the more than 6 million children (as of December 2021) internationally who have been vaccinated at least once. The data currently available confirm the efficacy and safety of the vaccine. New data are being collected and reviewed by experts on an ongoing basis.

- Other health problems – unrelated to the vaccination – may continue to arise, sometimes directly after a vaccination. This does not mean that they are necessarily a consequence of the vaccination.

Important: Please report any unexpected or serious symptoms experienced after the COVID-19 vaccination to a paediatrician or the vaccination centre

You should not have your child vaccinated in the following case:

- If you know that your child suffers from hypersensitivity to components of the vaccine – in particular to polyethylene glycol (PEG) or tromethamine (TRIS).

The vaccination is currently not yet recommended in the following cases:

- For children under 5
Insufficient data is currently available on the use of the vaccine for this group.
- Recovered children without a specific recommendation (see below)

Caution is advised for the vaccination in the following cases:

- If your child is currently ill and has a temperature (>38.5°C).
➔ In this case, you should postpone the vaccination.
- If your child has an acute allergy or takes blood-thinning medication.
➔ In both cases, you should inform the professional at the vaccination centre so that they can take special precautions, or talk to your paediatrician beforehand.
- If your child had a severe allergic reaction after the first vaccine dose.
➔ You should only have your child vaccinated a second time in exceptional cases. Please talk to your paediatrician about the next steps.

Vaccination after a confirmed coronavirus infection

- The vaccination is only recommended for children who have already had a coronavirus infection if they belong to groups a) or b) mentioned above. Vaccination is possible from 4 weeks after the infection.
- No vaccination is currently recommended for any other children who have recovered from COVID-19.





- However, from a medical point of view it is quite safe to vaccinate a child who has already had an (undetected) infection.
- If your child has a weakened immune system (because of an illness or therapy), please discuss what to do with your paediatrician.

Important information for after the vaccination

- Make sure you receive a vaccination certificate and keep it somewhere safe.
- Have you already been given your second vaccination appointment? Your child should have the second injection about four weeks after the first. Both vaccinations should be done with the Pfizer/BioNTech mRNA vaccine for children.
- The full protection of the vaccination will have been built up one to two weeks after the second dose.
- Please report any severe or unexpected symptoms experienced after the COVID-19 vaccination to your paediatrician or the vaccination centre.
- Does your child have symptoms of COVID-19 despite the vaccination?
Then have your child tested. The rules for isolation also apply to vaccinated children who have tested positive.

Do you have any questions? You should discuss these with the professional vaccinating your child.

This fact sheet does not replace the vaccination discussion with a professional.

