Factsheet: COVID-19 vaccination with Nuvaxovid®
(protein-based vaccine – manufactured by Novavax)

Why does vaccination against 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 the healthcare system 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.
- Nuvaxovid® contains the recombinant spike protein of the SARS-CoV-2 virus and an adjuvant.
- Nuvaxovid® has demonstrated a very good efficacy and safety profile in clinical trials (data only up to the Alpha variant). 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.*

General vaccination strategy[1]

According to the vaccination strategy and vaccination recommendations formulated by the Federal Commission for Vaccination (FCV) and the Federal Office of Public Health (FOPH), vaccination against COVID-19 is recommended for everyone aged 5 years and over (please note: people aged 5-17 years only with mRNA vaccines).
This recommendation applies in particular to persons at increased risk of severe disease (particularly vulnerable persons) and their close contacts. The Swiss COVID-19 vaccination strategy is based primarily on mRNA vaccines. This vaccine technology is currently proving to be very effective and safe in widespread use. The vaccination recommendation for the protein-based vaccine Nuvaxovid® follows the vaccination recommendations for mRNA vaccines and viral vector vaccines and expands the range of available vaccines against COVID-19 as needed.

Indication for vaccination with Nuvaxovid®

Recommended for individuals 18 years of age and older apart from pregnancy or breastfeeding who, for medical reasons, cannot be vaccinated with an mRNA vaccine or who refuse mRNA vaccines.[2]

Vaccination with Nuvaxovid® is not recommended for:

- This vaccine is not authorised and not recommended for children and adolescents under 18 years of age since no data are available on the use of the vaccine in this age group. Vaccination with an mRNA vaccine is recommended from the age of 5 years.

Vaccination with Nuvaxovid® is not recommended for pregnant and breastfeeding women. Vaccination with the mRNA vaccines authorised in Switzerland is recommended from the second trimester of pregnancy and during breastfeeding.

Contraindication and indication after clarification of a reservation

Vaccination is contraindicated in cases of known hypersensitivity to ingredients in the vaccine[3] (e.g. Polysorbate 80, saponins, Matrix-M™).
Vaccination with mRNA vaccines is generally recommended for immunocompromised individuals. Use of Nuvaxovid® in immunocompromised individuals only after an individual benefit/risk assessment (efficacy, tolerability), particularly in comparison to vaccination with an mRNA vaccine.

The vaccination recommendations contain further details of precautions and information on vaccination of people who are known to have severe acute allergies.[4]

Vaccine[3]

Nuvaxovid® is a vaccine that contains a genetically engineered recombinant, full-length SARS-CoV-2 spike protein. The spike protein is produced using an insect cell line and purified. The addition of the saponin-based adjuvant Matrix-M™ promotes the activation of innate immune cells, which increases the extent of the spike protein-specific immune response. Both vaccine components trigger B-cell and T-cell immune responses to the spike protein, including neutralising antibodies that help protect against COVID-19.

Efficacy

Please note: the following information relates to SARS-CoV-2 virus variants before the appearance of the Delta variant. There is not yet any clinical efficacy data available from studies looking at the virus variants Delta and Omicron.

In the registration studies, 7 days after the 2nd dose, Nuvaxovid® provided protection against symptomatic COVID-19 infection of approx. 90% (95% CI: approx. 80-95%) for the variants in circulation at the time of the studies (Wuhan and Alpha). Nuvaxovid® therefore showed comparable efficacy to mRNA vaccines in terms of protecting against symptomatic and severe COVID-19 infection. However, Nuvaxovid® showed reduced efficacy of around 50% (95% CI: 17-71%) against symptomatic COVID-19 infection caused by the Beta variant.

The duration of protection from the vaccine is not known as it is still being investigated in ongoing clinical trials. Information on the need for a booster vaccination will be provided in a timely manner, if required.

Known side effects

The results of clinical trials show that the vaccines are well tolerated. However, they can be associated with mild to moderate side effects that resolve within a few days. The most common side effects are local reactions of the type that can also occur with other vaccinations. The most frequent side effects include injection site tenderness (75%), injection site pain (62%), fatigue (53%), myalgia (51%), headache (50%), malaise (41%), arthralgia (24%) and nausea or vomiting (15%) [3].

[1] Vaccination strategy and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen – (available in German and French only)
[2] For the definition of the contraindications for mRNA vaccination, see mRNA vaccination recommendations and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen – (available in German and French only)
[3] www.swissmedicinfo.ch
[4] Nuvaxovid vaccination recommendations: www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen – available in German and French

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Adverse reactions were usually mild to moderate in severity with a median duration of less than or equal to 2 days for local events and less than or equal to 1 day for systemic events following vaccination.
Local and systemic side effects were reported more frequently after the 2nd dose than after the 1st dose.

Severe allergic reactions to a component of the vaccine are very rare. They usually occur immediately after vaccination. Initial signs of a severe reaction, such as shortness of breath, a drop in blood pressure and severe reactions at the injection site, usually develop within minutes.

The risk of other 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 these side effects occurring is very low. The institutions in charge observe possible signs closely. Other health problems may also occur, sometimes with a direct temporal relationship to vaccination. This does not mean, however, that they are necessarily a result of the vaccination.
A doctor, pharmacist or vaccination centre should be notified of any serious or unexpected side effects. These notifications are recorded in the Swissmedic vigilance system.[5] If necessary, action will be taken based on this.

Vaccination schedule

Initial immunisation
The initial immunisation consists of 2 injections i.m. into the deltoid muscle around 4 weeks apart (minimum interval according to authorisation: 3 weeks).
Expected protection provided by the vaccine appears approx. 1-2 weeks after the 2nd injection.

Note on initial immunisation:
By analogy with mRNA vaccines, vaccination of individuals with a confirmed SARS-CoV-2 infection[6] is recommended promptly between 4 weeks and 3 months after the infection. There is no upper time limit for vaccination following an infection.
A heterologous vaccination schedule (1 dose of Nuvaxovid® before or after receiving an mRNA or viral vector vaccine) is outside the scope of authorisation (off-label) and is not generally recommended. Exception: people who had an anaphylactic reaction after receiving an mRNA vaccine, after a benefit/risk assessment by a specialist doctor[7].
Serological testing is generally not recommended and should not be performed explicitly to determine the vaccination schedule.
The vaccination should be postponed in the event of acute febrile illness.

Booster vaccination/additional doses
A booster vaccination with Nuvaxovid® is not currently authorised and not generally recommended. People who had an anaphylactic reaction after receiving an mRNA vaccine can receive a heterologous booster vaccination with Nuvaxovid® after a benefit/risk assessment by a specialist doctor[7].

Care after the vaccination

Given that all vaccinations entail the risk of allergic reaction, a doctor or qualified pharmacist should be available to provide assistance. 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 informed about possible side effects and what to do if they occur. This applies particularly 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.
The general recommendations on hygiene and social distancing must continue to be observed before, during and also after the vaccination. There is no minimum interval to other vaccinations.

Availability of the vaccine

Responsibility for organising vaccinations against 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
→ FOPH Infoline health care professionals: +41 58 462 21 00
→ www.infovac.ch
→ www.foph-coronavirus.ch/vaccination/

[5] www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/pharmacovigilance/elvis.html
[6] Statements and consequences of various SARS-CoV-2 tests and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - English Documents
[7] See Chapter 10.5 of the mRNA vaccination recommendation and documents for healthcare professionals – (available in German and French only).

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