Fact sheet: Vaccination with COVID-19 Vaccine Janssen® (adenoviral vector vaccine Janssen-Cilag)

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 in particular and people *with chronic diseases* are at a significantly higher risk of suffering a severe case of the disease with complications such as hospitalisation and death.
- *Younger people without chronic diseases* can also suffer severe cases and 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 of the *healthcare system* being overwhelmed due to the large number of severe cases, meaning that care could no longer be fully guaranteed for the population.
- The vector used in COVID-19 Vaccine Janssen® is a genetically modified, replication-incompetent adenovirus (Ad26.COV2-S) that is harmless for people. Adenovirus vectors have been researched for many years as part of work to develop vaccines and they are already in use.
- COVID-19 Vaccine Janssen® shows a good efficacy and safety profile in clinical trials and in observational studies (data up to and including Delta variant). Vaccination is much safer for individuals than an infection and its potentially severe complications.
- This leads to a major reduction in the number of severe cases and deaths, and thus to a reduction in *hospitalisations*.

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 only with mRNA vaccines).
This recommendation applies in particular to persons at increased risk of severe disease (especially vulnerable persons, VP) 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 adenoviral vector vaccine COVID-19 Vaccine Janssen® follows the vaccination recommendations for mRNA vaccines and expands the range of available vaccines against COVID-19 as needed.

Indication for vaccination with COVID-19 Vaccine Janssen®

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

Vaccination with COVID-19 Vaccine Janssen® is not recommended for:

- This vaccine is not recommended for children and adolescents under 18 years of age since no data on the use of the vaccine are available. Vaccination with an mRNA vaccine is recommended from the age of 5 years.
- Vaccination with COVID-19 Vaccine Janssen® is not recommended for pregnant and lactating women. Vaccination with the mRNA vaccines authorised in Switzerland is recommended from the second trimester and during lactation. Based on the currently available data and comparisons with an mRNA vaccine, COVID-19 Vaccine Janssen® should be considered only if the potential individual benefit clearly outweighs the potential risks to the mother and foetus.

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).
- Vaccination is contraindicated in people who have had a history of capillary leak syndrome (CLS).
- Vaccination with mRNA vaccines is generally recommended for immunocompromised individuals. Use in immunocompromised individuals only after an individual benefit/risk assessment (efficacy, tolerability), particularly compared 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]

This is a vector-based vaccine that uses a genetically modified, replication-incompetent adenovirus vector (Ad26.COV2-S) that is harmless for people. The vector contains the genetic information for the SARS-CoV-2 spike protein. After the vaccine has been administered, the vector penetrates some cells in the body and the vector DNA passes into the cell nucleus. The *viral spike protein (antigen)* is produced in these cells. This stimulates the immune system to respond with an immune reaction involving the formation of antibodies and cellular defence against SARS-CoV-2. The possibility of the vector DNA integrating into the human genome cannot be completely excluded. However, this can also happen with viral infections. The natural turnover of cells and the elimination of antigen-presenting cells by the immune system mean that it is extremely unlikely that the vector DNA will remain in the body permanently. Clinical experience with these vectors obtained over several years has not indicated any side effects of this kind.

Efficacy

Please note: the following information relates to SARS-CoV-2 virus variants before the appearance of the Omicron variant. For data on the Omicron variant, see the end of this section.
The authorisation studies show that the vector vaccine from Janssen offers good protection against moderate illness due to COVID-19 (including the Alpha, Beta and Gamma P2 virus variants) of approx. 65% (95% CI 56-72%) and very good protection against severe illness of approx. 85% (95% CI 54-97%). Good protection has also been demonstrated in older people. Data on protection against the variants Gamma P1 and Delta are still awaited. However, US data from observational studies for the period March-August 2021 show a protection against hospitalisations of around 70% (compared to 88-93% for the mRNA vaccines).
A few months after the injection, the protection provided by vaccination with COVID-19 Vaccine Janssen®, particularly against the new virus variants, decreases significantly. Depending on the vaccine, the level of protection from vaccination can be increased moderately to well by giving an additional dose.
Note on the data regarding the Omicron variant:
Unlike previous variants, initial evidence suggests significantly reduced protection against the Omicron variant in people who received a first dose of COVID-19 Vaccine Janssen® for the initial immunisation. A heterologous booster vaccination (COVID-19 Vaccine Janssen® followed by an mRNA vaccine) increases the concentration of neutralising antibodies against Omicron compared with a homologous booster vaccination.

[1] Vaccination strategy and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen – COVID-19 vaccination
[2] For the definition of the contraindications for mRNA vaccination, see the mRNA vaccination recommendations and www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen – COVID-19 vaccination.
[3] www.swissmedicinfo.ch
[4] Janssen vaccination recommendation or www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen – Covid-19-Impfung. (German and French only)

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 pain and swelling at the injection site, fatigue, muscle pain and headaches (30-50%)[3]. High temperature and nausea may also occur (10-20%). These reactions are usually mild to moderate in intensity and of brief duration. Older people have fewer side effects.
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.
Data from individual studies show that the reactogenicity of a booster dose with COVID-19 Vaccine Janssen® is similar to that of the first dose of COVID-19 Vaccine Janssen®.

Thrombosis with thrombocytopenia syndrome (TTS)
A very rare and serious combination of thrombosis and thrombocytopenia accompanied by bleeding has been observed in a very small number of people following vaccination with COVID-19 Vaccine Janssen® since market launch. According to Swissmedic, the reports particularly involved women under 60 years of age (estimated frequency according to the CDC in those aged under 50: 8 in 1,000,000; 50 and over: 1 in 1,000,000). This includes cases which presented as venous thrombosis, including manifestation in unusual locations such as cerebral venous sinus thrombosis, splanchnic vein thrombosis and arterial thrombosis, with accompanying thrombocytopenia. Some cases had a fatal outcome. Most of these cases occurred within the first 3 weeks after vaccination. A causal relationship is thought to be plausible internationally.
According to current knowledge, TTS can affect all age groups and both genders after vaccination with COVID-19 Vaccine Janssen®. No specific risk factors have been identified so far.
People should be informed about these very rare potential complications before being vaccinated.

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 on this basis.

Vaccination schedule

Initial immunisation:
The initial immunisation consists of 1 injection into the deltoid muscle. Expected protection provided by the vaccine appears approx. 3 weeks after injection. The latest evidence suggests that this protection against the Omicron variant is insufficient. The immune response after a heterologous 2-dose vaccination schedule (viral vector vaccine/mRNA vaccine) is superior to the immune response after a single dose of COVID-19 Vaccine Janssen®. People who received a single dose of COVID-19 Vaccine Janssen® less than 4 months ago are therefore advised to supplement their initial immunisation with a dose of an mRNA vaccine[6,7]. A minimum period of 28 days should be observed after the 1st dose of vaccine against COVID-19.

Note on initial immunisation: By analogy with mRNA vaccines, vaccination of individuals with a confirmed SARS-CoV-2 infection[8] is recommended promptly between 4 weeks and 3 months after the infection. There is no upper time limit for vaccination following an infection.
Serological testing is not generally recommended and should not be performed explicitly to determine the vaccination schedule.
Vaccination should be postponed in the event of acute febrile illness.

Booster vaccination/additional doses:
The booster is recommended at earliest 4 months[6] after the last dose of the initial immunisation with an mRNA vaccine[9]. The booster can be administered with Spikevax® or Comirnaty® (exception: people aged under 30 preferably/exclusively recommended Comirnaty® depending on age.). The current evidence suggests that a heterologous booster vaccination with Spikevax® or Comirnaty® after COVID-19 Vaccine Janssen® is well tolerated and immunogenic. In principle, a booster vaccination with COVID-19 Vaccine Janssen® is also possible for people who were initially immunised with an mRNA vaccine.

Explicitly only for those who cannot receive an mRNA vaccine for medical reasons, or who are unwilling to receive it, a 2nd dose of COVID-19 Vaccine Janssen® is recommended from 2 months after the initial immunisation with a dose of COVID-19 Vaccine Janssen®[10].

Note on booster vaccination: if a confirmed SARS-CoV-2 infection occurs within 4 months of completion of the initial immunisation, a booster with an mRNA vaccine (or a second dose of COVID-19 Vaccine Janssen®) is recommended **at the earliest 4 months[6]** after this infection. Please note: a confirmed infection more than 4 months after the initial immunisation is deemed a booster and no additional vaccine dose is needed. In people at especially high risk and those who are particularly exposed (e.g. healthcare workers), an additional dose of vaccine may be recommended in individual cases if the infection was more than 4 months ago[6,11].

[5] www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/marktueberwachung/pharmacovigilance/elvis.htm
[6] Certain recommendations deviate from the approval (off-label). If the professional responsible bases their choice or use of a vaccine on the FOPH vaccination recommendations, they can prove that they have observed the recognised rules of medical and pharmaceutical science and have thus complied with the due diligence rules under the Therapeutic Products Act. If the professional responsible also complies with the duties of care arising from the treatment contract (including the duty to inform, explain and document), they cannot usually be held liable (see also FOPH Bulletin 2015; 13:217, only available in German).
[7] 0,3 mL (30 µg) Comirnaty® or 0,5 mL (100 µg) Spikevax®; see factsheet mRNA vaccines on www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen
[8] Statements and consequences of various SARS-CoV-2 tests and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - COVID-19 testing
[9] For detailed information on mRNA vaccines, see Fact sheet mRNA vaccines at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen
[10] According to the Swissmedic authorisation, people are entitled to a certificate of initial immunisation after one dose of COVID-19 Vaccine Janssen® and to a certificate of booster vaccination after a 2nd dose of COVID-19 Vaccine Janssen® after 2 months or more.
[11] Vaccination recommendation mRNA vaccines and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen

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More information

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.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism, thrombocytopenia and coagulopathies. Vaccinated individuals should be instructed to consult a doctor immediately if, between a few days and 3 weeks after vaccination, they develop symptoms such as severe or persistent headaches, blurred vision, confusion, mood changes, seizures, shortness of breath, chest pain, leg swellings, leg pain, persistent abdominal pain or unusual skin bruising and/or petechiae.

People diagnosed with thrombocytopenia or thrombosis within 3 weeks of being vaccinated with COVID-19 Vaccine Janssen® should actively watch out for signs of the other condition so that the possibility of TTS can be investigated. TTS requires special clinical treatment. Healthcare professionals should observe the current guidelines and/or consult specialists (e.g. haematologists, coagulation specialists) when diagnosing and treating this condition[4].

The generally recommended hygiene and behavioural rules must continue to be observed before, during and also after the vaccination. There is no minimum interval to other vaccinations.

Availability of vaccinations

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
→ www.infovac.ch
→ www.foph-coronavirus.ch/vaccination/

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More information