Checklist for administration of COVID-19 Vaccine Janssen®
(adenoviral vector vaccine Janssen-Cilag)

Specifically before 1st injection

Administrative clarification	Clarify how the person to be vaccinated is insured (compulsory health insurance/insurance card) Verify the identity of the person to be vaccinated
Clarification of the indication for vaccination	The Swiss COVID-19 vaccination strategy is based primarily on mRNA vaccines 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. Contraindications for mRNA vaccines: – Anaphylaxis or severe general reaction to ingredients in the vaccine, – Known or probable immediate-type hypersensitivity to polyethylene glycol (PEG, Macrogol) or tromethamine (trometamol, TRIS) – Anaphylaxis after the first dose of mRNA vaccine. Clarification and consultation with a specialist in allergies and clinical immunology recommended Based on the current vaccination recommendations of the FCV/FOPH www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen (available in German or French)
Vaccine schedule according to the FCV/FOPH recommendation →	Initial immunisation: 1st dose of COVID-19 Vaccine Janssen®. Supplemental dose of mRNA vaccine recommended after at least 28 days[1] If mRNA not possible for medical reasons or patient unwilling to receive it: 2nd dose of COVID-19 Vaccine Janssen® recommended after at least 2 months
Clarification of contraindications	Known hypersensitivity to ingredients of the vaccine (e.g. polysorbate 80) Individuals with a history of capillary leak syndrome
Vaccination currently not recommended	Children and adolescents (<18 years) Pregnant women
Clarification of special precautions	1. Generally known hypersensitivity reactions/allergies? 2. Immunodeficiency (congenital, acquired, immunosuppressant treatment, including during cancer treatment) Vaccination with mRNA vaccines is generally recommended for immunocompromised individuals. Indication for vaccination with COVID-19 Vaccine Janssen® after a careful benefit/risk assessment (efficacy, tolerability), particularly compared to vaccination with an mRNA vaccine, by the treating specialist and after a corresponding briefing. Vaccination recommendations; also at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen (available in German and French)

Before 2nd injection / booster

Clarification of indication for 2nd injection	In principle, a supplement to the initial immunisation with a dose of mRNA vaccine[1] is recommended after at least 28 days (for procedure, see Checklist mRNA) A booster is recommended with an mRNA vaccine, earliest 4 months after initial immunisation[1]. A 2nd dose of COVID-19 Vaccine Janssen® is recommended after at least 2 months exclusively for people who cannot receive an mRNA vaccine for medical reasons, or are unwilling to receive an mRNA vaccine. Booster vaccination with COVID-19 Vaccine Janssen® is possible after ≥ 4 months[1] for those aged 18 or over who were initially immunised with an mRNA vaccine.
Adverse vaccine reactions (AVRs) after first injection?	Document using IT-Tool Severe or unexpected adverse vaccination reactions must be reported to Swissmedic by the healthcare professional who identifies the AVR. If an anaphylactic reaction occurs after the first vaccine dose, the 2nd dose is contraindicated for the time being and requires clarification and confirmation by a specialist in allergology and clinical immunology. If thrombosis and thrombocytopenia occur after the 1st vaccine dose, the 2nd dose should only be administered following consultation with a specialist doctor after conducting a personal risk-benefit analysis. For more detailed information, please see the Vaccination recommendation (available in German or French only).
AVR reporting to Swissmedic	Via link to the “ELViS” reporting system in the IT-Tool www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/pharmacovigilance/elvis.html
COVID-19 medical history	Confirmed SARS-CoV-2 infection **before the first vaccine dose** of COVID-19 Vaccine Janssen®: Vaccination with one dose recommended promptly from 4 weeks after infection and within 3 months Confirmed SARS-CoV-2 infection **after the first vaccine dose** of COVID-19 Vaccine Janssen®: Booster is recommended at least 4 months after this infection. Important: a confirmed infection > 4 months after the initial immunisation is deemed a booster and no additional vaccine dose is necessary (for more detailed information, see the Vaccination recommendation). Statements and consequences of various SARS-CoV-2 tests and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen- English documents

[1] Some recommendations differ from the authorisation (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.

✔ Procedure for 1st injection / 2nd injection / booster

Current general health	Clarify current general health and decide: Can the vaccination proceed today? Acute febrile illness (fever)? Postpone vaccination until the symptoms have subsided.
Client briefing	Does the person to be vaccinated have any questions? Has he/she read the information material (e.g. FOPH fact sheet/information sheet)? Mention possible AVRs, particularly possible allergic reactions signs of thromboembolism and thrombocytopenia: from a few days to 3 weeks after vaccination, 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, unusual skin bruising, petechiae
Client consent	Obtain oral consent to the vaccination from the person to be vaccinated on the basis of an informed consent and to the electronic recording of the vaccination in the data entry system Make a written note of the consent to vaccination in the vaccination data sheet/IT tool If the person is incapable of giving consent, the consent must be obtained from his/her legal representative
Completing the vaccination data sheet / recording in IT tool	Enter the relevant details of the person to be vaccinated in the IT tool
Preparing the vaccine	See manufacturer's information sheet: www.bbraun.ch/kit-covid19 / www.covid19vaccinejanssen.com Gently swirl the vaccine vials without shaking If possible, the stopper should only be pierced once with the needle, and the movement of the needle should be minimised.
Administering the vaccine	See manufacturer's information sheet: www.bbraun.ch/kit-covid19 / www.covid19vaccinejanssen.com One vaccine dose i.m. in deltoid muscle For anticoagulated patients: The vaccine is also injected intramuscularly, and subsequent firm compression is important www.bag.admin.ch/impfplan (available in German, French and Italian)

✔ After all vaccine doses

Explain how to behave in the event of an AVR	Tell the client to report any serious or unexpected AVRs to a doctor/pharmacist/vaccination site. If applicable, give the client a contact number. Reporting via link to the "ELVIS" reporting system in the IT tool www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/pharmacovigilance/elvis.html
Explain how to behave generally after injection	Expected protection provided by the vaccine appears 3 weeks after the 1st injection. It should be borne in mind that protection against Omicron is greatly reduced after just one dose and a supplementary dose of an mRNA vaccine is therefore recommended after 28 days (or a 2nd dose of COVID-19 Vaccine Janssen® after at least 2 months if an mRNA-vaccine is not possible). Continue to follow rules on social distancing and hygiene. If symptoms consistent with COVID-19 occur, carry out a test (vaccination not 100% effective) No minimal interval to other vaccines is necessary
Issuing a vaccination certificate	Issue the client with a vaccination certificate from the IT-Tool or make an entry in the vaccination record. If possible, stamp and signature of the person administering the vaccine. Affix/enter LOT number in the vaccination certificate. Information on the vaccination certificate (valid from the 22nd day after injection) and issue on request: COVID certificate (admin.ch)
Arrange follow-up appointment (if needed)	Note appointment at the same vaccination site in the IT-Tool. Give appointment card if appropriate. Give client information sheet with instructions on behaviour after the vaccination.
Observation time after injection	Trained healthcare personnel and an emergency kit including adrenaline must be available in case an allergic reaction takes place. Monitor particularly those who had experienced problems directly after the injection, e. g. circulatory problems. All people who are vaccinated should remain on the premises for at least 15 minutes after the 1st vaccination. If the 1st dose was well tolerated, an observation period of 5 minutes after subsequent doses is sufficient.