

PATIENT	Doctor supervising the pregnancy
LAST NAME First name:	LAST NAME Dr.
Date of birth:	E-mail:

PRESCRIPTION

DATE:

- SARS-CoV-2 vaccination with mRNA vaccine / 2 injections

Signature and stamp of the doctor:

PLEASE ATTACH THE FORM FOR RECORDING SIDE EFFECTS

– This prescription is valid for 2 injections –

Information for pregnant women on the vaccination with COVID-19 mRNA vaccine (version: 28.05.2021)

Dear Ms

Against the backdrop of the COVID-19 pandemic, this leaflet gives you some important information about the vaccine against the coronavirus during your pregnancy.

- **What risks does the COVID-19 coronavirus pose to pregnant women?**

In the event of an infection with the coronavirus, the risk of experiencing a serious form of the illness with the need for a hospital stay and treatment in intensive care is much higher for a pregnant women than for the corresponding age group of the general population. If the infection is very severe the birth may need to be medically induced (possibly even prematurely) in order to help the mother's breathing and ensure the health of the newborn baby. Also, the risk of a premature birth is around three times higher if a COVID-19 infection is contracted during pregnancy. **Pregnant women are therefore considered to be particularly vulnerable in connection with COVID-19.**

- **How can I protect myself during pregnancy?**

The principle of prevention applies. Pregnant women are advised to consistently follow the hygiene rules (frequent hand washing or hand disinfection). They should also avoid shaking hands, keep at least 1.5 metres away from other people, avoid heavily congested locations and busy times and wear a mask when outside the home. Within the family, their partner should follow the same rules, including wearing a mask outside the home and if spacing of 1.5 metres is not possible. If the pregnant woman or a family member experiences a suspicious symptom, a COVID-19 test must be arranged.

- **What is known about COVID-19 vaccination during pregnancy?**

Risks for the mother: Little information is currently available about the effects of COVID-19 vaccination during pregnancy. In animal studies, no adverse effects were observed on pregnancy, embryofetal development, birth or postnatal development. The currently authorized vaccines are (still) not generally recommended during pregnancy since the clinical data on safety is limited. However, no evidence of unexpected side effects on the mother or child has been found in over 200,000 pregnant women in the USA who have been vaccinated to date with an mRNA vaccine. In the studies connected with vaccine development, a fever higher than 38 °C occurred in 14.2 % of the participants aged between 18 and 55 after the first dose, and possibly in a higher percentage after the second dose. Other possible, but rarer, side effects reported included swelling or pain at the injection site, fatigue, headache and muscle or joint pain. Most symptoms subsided within two days. These known temporary side effects do not occur more often in pregnant women than in non-pregnant individuals of the same age.

Risks for the unborn child: Vaccines are not generally associated with a risk of foetal malformations. The two COVID-19 vaccines currently authorized in Switzerland are known as mRNA vaccines. They contain genetic material that codes for an SARS-COV-2 surface protein. mRNA cannot be incorporated into the DNA of human cells since mRNA does not enter the cell nucleus. Consequently, there is no risk of any genetic alteration in female patients who are given the vaccine or in their unborn children. Nor have any foetal malformations caused by the vaccine constituents been reported in clinical trials with over 1,000 women who were vaccinated in the 1st trimester of pregnancy.

Advantages: After two doses of COVID-19 vaccine given 4 weeks apart, the efficacy of the mRNA vaccines authorized in Switzerland two weeks after the second dose was 95 %. The benefit of a single dose is much lower. Studies that have investigated the efficacy of the vaccine to date in pregnant women have shown that there is probably no difference compared to the efficacy in the corresponding age group of the general

population. You and your gynaecologist will weigh up the risks and benefits of vaccination against the risk of COVID-19. The risks and side effects of the above-mentioned vaccine should be weighed against the risk of a severe COVID-19 infection in the mother (5 %) and her child. In pregnant women with the chronic illnesses listed above, the risk of the mothers suffering a severe episode is especially high. Particularly in these patients, but also in women with a high exposure risk, the advantages of COVID-19 vaccination appear to outweigh the possible vaccine side effects.

- **When can vaccination be considered during pregnancy?**

Currently, vaccination against COVID-19 is recommended for pregnant women with chronic illnesses (according to the FOPH list) or with an increased exposure risk. All other pregnant women have the option of being vaccinated on request. In any case, you and your gynaecologist should carry out a benefit-risk analysis before you decide whether or not to be vaccinated with a COVID-19 vaccine. Moreover, as a precaution, the vaccine should be administered only in the 2nd or 3rd trimester, not in the 1st trimester. If you agree to be vaccinated, you will be offered the option of follow-up so that any side effects of the vaccination can be recorded and reported. When the vaccination is prescribed, you will be given a form for recording possible side effects. Please complete this report form for possible side effects and bring it with you to your next appointment with your gynaecologist. If you agree (by signing the attached informed consent form), he or she will then send the form, together details on the outcome of your pregnancy, to a registry at Lausanne University Hospital (CHUV). As with all medicines, any side effects of the vaccine are reported to Swissmedic.

Informed consent form for the expectant mother and treatment mandate.

I hereby declare that I have

- reached my decision together with my doctor
- been given sufficient time to think before making my decision
- been informed about the advantages and disadvantages of this vaccination (Information on vaccination: <https://foph-coronavirus.ch/vaccination/>)

I consent to the vaccination against COVID-19.

NO **YES**

(if yes, prescribe the COVID-19 vaccine for the patient)

Place, date _____

Duration of the informed consent discussion: _____

Surname / first name of the pregnant woman _____

The doctor _____