

COVID-19 VACCINE: FREQUENTLY ASKED QUESTIONS

This content has been modified from the document: MMS Response to COVID-19 Vaccine (11 January 2021)

How is the COVID-19 vaccine administered?

The COVID-19 vaccines are intramuscular (IM) injections. For the Pfizer/BioNTech vaccine a second booster is necessary 3 weeks after the initial injection, whilst for the AstraZeneca vaccine the second booster is required 4 – 12 weeks after the initial injection.

Are the COVID-19 vaccines recommended for mitochondrial disease (mito) patients?

Clinical trials have not been conducted in patients with rare diseases or children. Although knowledge concerning all the potential vaccine effects in is currently unknown, the safety profile of the vaccines so far suggests that the benefit of preventing COVID-19 infection outweigh the risk of vaccine reaction. We do expect patients with mito to have a similar response to the vaccine as the general population.

Are there any specific precautions that I need to take if I, or my child have a form of mito?

You should always discuss your health care with your doctor or clinical nurse consultant or practitioner. Patients who have immune deficiencies or other serious complications from their mito could be at risk of worsening of their mito symptoms if the side effects produce fever, loss of appetite, inability to hydrate, diarrhea or vomiting. The safety profile of the vaccines so far suggests that the benefits of preventing COVID-19 infection outweigh the risk of vaccine reactions. The knowledge of prior reactions and experiences with other vaccines such as the flu vaccine can be a helpful guide for making a plan if such side effects occur.

Can I get COVID-19 from a vaccine? Can I transmit it to other people?

No. The vaccines do not contain the full live SARS-CoV-2 virus and cannot cause COVID-19 infection. The Pfizer/BioNTech vaccine contains non-infectious genetic material (mRNA) that is quickly destroyed by the body. The AstraZeneca vaccine is an adenovirus (completely unrelated to the SARS-CoV-2 virus) vaccine encoding the SARS-CoV-2 spike protein, which trains the immune system to remove the SARS-CoV-2 virus.

It typically takes a few weeks for the body to build immunity after vaccination. It is therefore possible that a person could become infected with COVID-19 just before or just after vaccination and become unwell. This is because the vaccine has not had enough time to provide protection. If this happens, please call your health care providers to discuss your management.

You also cannot pass COVID-19 to your family if you get vaccinated. If you become ill with COVID-19 in the days or first few weeks after vaccination and before the vaccine has time to become effective, then you could still transmit virus to your family. At this time, we still don't know if the vaccine prevents transmission, and therefore, you should continue to practice the same precautions as you are now to

prevent transmitting COVID-19 to family members who are not part of your immediate household.

What are the side effects from the vaccine?

The most common reported symptoms from the vaccine have been local reactions at the site of vaccination (pain, soreness), similar to the flu vaccine. Some systemic effects such as fatigue, headache, muscle pain, joint pain and chills have also been observed in some people and are generally of short duration (a few hours to a few days).

There are differences between injection reactions which can be mild to severe and mimic the COVID-19 infection and allergic reactions that may rarely be life threatening.

Allergic reactions to vaccines are very rare (about 1 in 1 million people will have an allergic reaction to a vaccine). Some reactions are mild (hives), but others can be severe (anaphylaxis). Allergic reaction symptoms start very quickly after the injection (within minutes to 4 hours of vaccination) and typically include diffuse skin hives; body part swelling (mouth, lips, tongue or throat); breathing difficulties (shortness of breath, wheezing, chest tightness); or low blood pressure or loss of consciousness. About half of allergic reactions to vaccines happen in the first 15 minutes after receiving the vaccination. For this reason, vaccines need to be administered in a controlled medical setting and the patient should be observed for at least 15 minutes after the injection to detect any possible allergic reaction needing urgent treatment. These are the symptoms that may develop after the vaccination:

Injection reactions occurring within 3 days of the vaccination, counting the day of vaccination as day 1.

These can last several days and although uncomfortable there is **no risk** of an allergic reaction with the next vaccination.

- 1) Local injection site reaction is quite common and expected to occur in 8 out of 10 people. (i.e., redness, soreness or swelling at the injection site)
- 2) Mild post vaccination reaction, which is also common and including: feeling feverish with temperature less than 37.8°C, mild headache, new or worsening fatigue, mild muscle aches, and mild joint pains.
- 3) Moderate or severe symptoms are uncommon, including fever of 37.8°C or greater, moderate/severe headache, moderate/severe fatigue, moderate/severe muscle aches, moderate/severe joint pains. These can be associated with any of the following new or progressive symptoms consistent with COVID-19 such as sore throat, new cough, new nasal congestion, new runny nose, new loss of smell or taste or shortness of breath

Allergic reactions occurring within minutes to hours of the vaccination.

Different ingredients in vaccines, including gelatin, egg, and excipients (inactive ingredients such as polyethylene glycol (PEG) and polysorbates) can cause an allergic reaction.

PEG is a water-soluble ingredient used in a variety of commercial products, medications and vaccines (> 1000 FDA approved medications). It is found in commonly used colonoscopy preparations or constipation treatment, IV PEGylated

medications, ultrasound gel and injectable steroid injections such as methylprednisolone acetate. Reactions to polyethylene glycol are exceedingly rare but anaphylaxis has been reported.

The Pfizer/BioNTech vaccine contains PEG. The AstraZeneca vaccine contains polysorbate but not PEG. Neither vaccine contains gelatin, egg, gluten or any animal products.

- 1) Mild allergic symptoms (i.e., itching, rash but NOT hives) are uncommon and occur after the initial observation period of 15 min post vaccine injection.
- 2) More severe allergic reactions are very rare and include hives, swollen lips, tongue, eyes, or face, wheezing, chest tightness, or shortness of breath. If you develop any of these symptoms, please call your national emergency telephone number or go to the nearest Emergency Department immediately.

If I had vaccine reactions in the past (with non-COVID-19 vaccines), are there any precautions I should take?

Some patients with mito may have developed high fevers and other symptoms with their routine vaccination. Before you receive your COVID-19 vaccine, you should discuss this with your treating health care provider to evaluate if certain precautions like taking paracetamol or ibuprofen prior to the vaccine and up to 24 hours afterwards, might be appropriate for you. Other interventions, if you develop vaccine reactions as described above, might be to make sure that supportive care is available for you and your child including appropriate hydration and caloric intake.

What if I have a history of severe allergy to a vaccine?

There have been only a few reports of severe allergic responses to the COVID-19 vaccines, mainly in association with the Pfizer/BioNTech vaccine. Anaphylaxis which is a severe allergic reaction that involves multiple body systems was observed in a few people who had a history of food or medication allergy. If you have a history of severe allergic reactions to a vaccine or its ingredients, it is recommended that you discuss the risk of receiving the vaccine with your doctor.

Are patients with mito considered “at risk patients” and can they get the vaccine in the first wave?

Immune deficiency may be seen in some individuals with mito disease, and so mito patients may be at increased risk of COVID-19 infection. In addition, mito individuals who have certain comorbidities such as heart disease, diabetes, severe myopathy with respiratory involvement, or severe metabolic decompensation with minimal stress, may be at risk of severe COVID-19 infection. However, internationally so far, there does not seem to have been an increased incidence of infection in individuals with mito.

The COVID vaccine program is being rolled out in five phases. Based on the [COVID-19 Vaccine Eligibility Checker](#), adult individuals with mito may expect to be able to receive during phase 1b of the rollout, particularly if they have these comorbidities.

According to the eligibility checker, children will not be eligible until phase 3 of the rollout. At this point in time, it is not clear whether children with comorbidities caused

by mito that could put them at increased risk for severe COVID-19 infection might be prioritised for the vaccines.

If I have had COVID-19, do I still need the vaccine?

Yes, even if you have had COVID-19 and developed symptoms from it, you should still be vaccinated.

How long will immunity last after I get vaccinated? Will I need to be vaccinated every year?

This information is still being investigated. At this time, we do not know how long the immunity conferred by the vaccine will last. We will have to wait for long-term data to become available to guide future vaccine protocols.

If I feel unwell or have side effects after getting the first dose, should I get the second dose?

If you have had mild side effects from the vaccine, these should resolve within a day or so and you should get your second dose as prescribed. If you have developed more severe side effects, you should be evaluated by your treating physicians to see if there are any contraindications to a second dose.

What happens if I only receive one dose of the vaccine and not both?

It is recommended to receive both doses of the vaccine to achieve maximum effectiveness. If you only receive one vaccine dose, the effectiveness may be reduced, and immunity to COVID-19 may not be guaranteed.

If I am unwell (sniffles, achy, cold symptoms...), should I still get the vaccine, or do I need to reschedule?

If you have any symptoms, you should stay home and contact your health care providers as you would normally do. Your vaccine will need to be rescheduled.

If I am exposed to COVID-19 infection between doses, what should I do?

There are no changes to definitions of exposure for vaccinated individuals. Exposure Investigations and Contact Tracing Policy following your state and public health guidelines will have to be followed regardless of vaccination status.

Could receiving the vaccine cause a false positive COVID-19 test?

No. The vaccine will not cause the standard COVID-19 tests (nasal swabs) to yield a false-positive response.

Is the vaccination safe for pregnant or breastfeeding women?

In preparation for vaccine roll-out, the [Australian Technical Advisory Group on Immunisation](#) has provided advice for breastfeeding and pregnant women for the Pfizer vaccine. This will be updated for the AstraZeneca vaccine. This advice will be provided as soon as it is received.

Will the vaccine affect my chance of getting pregnant in the future?

Vaccination is not believed to impact fertility or future offspring.

Will there be other vaccines for COVID-19?

Additional COVID-19 vaccines are being developed worldwide. Some will be very similar to the commonly used vaccine for the seasonal flu and some will be different.

Each vaccine will have to be individually reviewed to better understand the safety profile and efficacy.

Information and recommendations will evolve as more data are collected. Please obtain your information from scientific, trustworthy sources, such as those provided below.

Please see the newest COVID-19 updates here:

- 1) UMDF website: <https://www.umdf.org/coronavirus/>
- 2) Mitochondrial Medicine Society website: <http://www.mitosoc.org>
- 3) MitoAction website: <https://www.mitoaction.org/coronavirus/>.
- 4) GOV.UK website: <https://www.gov.uk/coronavirus>
- 5) NHS Rare Mitochondrial Disorders website: <https://mitochondrialdisease.nhs.uk/coronavirus/coronavirus-and-mitochondrial-disease/>
- 6) MITOCON website www.mitocon.it
- 7) ASMRM website: <http://asmrm.org/index.php>
- 8) CDC website: www.cdc.gov/coronavirus
<https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/checlist.html>
- 9) <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#authorised-medicines-section>
- 10) <https://ern-euro-nmd.eu>

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