

# Contraindications and Precautions to mRNA COVID-19 vaccination



# Updated contraindications and precautions to vaccination

- Recommendations apply to both Pfizer-BioNTech and Moderna COVID-19 vaccines
- Guidance may change as further information becomes available
- Definition of immediate allergic reaction to vaccine or medication:
  - Any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration

The screenshot shows the CDC website page for 'Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States'. The page includes a search bar, a navigation menu on the left, and a main content area with a yellow warning banner. The banner reads: 'Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites'. The main text discusses the ACIP's interim recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines, noting they are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines. It also mentions that these considerations are based on data submitted to the FDA and expert opinion. A section titled 'Authorized age groups' lists: Pfizer-BioNTech: ages ≥16 years; Moderna: ages ≥18 years. A section titled 'Administration' states that the mRNA COVID-19 vaccine series consist of two doses administered intramuscularly: Pfizer-BioNTech (30 µg, 0.3 ml each): three weeks (21 days) apart; Moderna (100 µg, 0.5 ml): one month (28 days) apart. A right-hand sidebar contains a table of contents with links to sections like 'Authorized age groups', 'Administration', 'Interchangeability with other COVID-19 vaccine products', etc.

# Contraindications to mRNA COVID-19 vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Contraindications to either of the mRNA COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to any of its components
  - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])\*
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)\*
- Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines

\* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

# Ingredients\* included in mRNA COVID-19 vaccines

Description	Pfizer-BioNTech	Moderna
mRNA	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	cholesterol	cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	potassium chloride	Tromethamine
	monobasic potassium phosphate	Tromethamine hydrochloride
	sodium chloride	Acetic acid
	dibasic sodium phosphate dihydrate	Sodium acetate
	sucrose	sucrose

\*As reported in the prescribing information

# Polyethylene glycol (PEG)

- Primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures
- Inactive ingredient or excipient in medications
- Used in a process called pegylation to improve therapeutic activity of some medications
- Cross-reactive hypersensitivity between PEG and polysorbates can occur
  - Polysorbates are included as an excipient in some vaccines and other therapeutic agents

Information on whether a medication contains PEG, a PEG derivative, or polysorbates can be found in the package insert. The NIH [DailyMed database](#) may also be used as a resource. Medications that contain PEG and/or polysorbate are described in the supplemental materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533-1540. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf>

# Distinguishing allergic reactions from other types of reactions

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
<b>Timing after vaccination</b>	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
<b>Signs and symptoms</b>			
<b>Constitutional</b>	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
<b>Cutaneous</b>	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
<b>Neurologic</b>	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
<b>Respiratory</b>	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
<b>Cardiovascular</b>	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
<b>Gastrointestinal</b>	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
<b>Musculoskeletal</b>	N/A	N/A	Myalgia, arthralgia
<b>Vaccine recommendations</b>			
<b>Receive 2<sup>nd</sup> dose of mRNA COVID-19</b>	No	Yes	Yes

# Neither contraindications nor precautions to vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- History of allergic reactions not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines, or polysorbates, including:
  - Food
  - Pet dander
  - Venom
  - Environment
  - Oral medications
  - Latex
  - Eggs
  - Gelatin