

Find the following information in this quick reference for pharmacy:

- Quick links and guidance
- Dosing and administration
- Storage

- Dose preparation
- Efficacy and safety information

- Clinical considerations
- Special populations
- Ingredients

Quick Links

- CDC: Frequently Asked Questions about COVID-19 Vaccination
- CDC: <u>Understanding and Explaining Viral Vector</u> COVID-19 Vaccines
- FDA: COVID-19 Vaccines

- CDC: V-safe After Vaccination Health Checker
- CDC: <u>VaxTextSM COVID-19</u> Vaccination Second-Dose Reminder
- USP: COVID-19 Vaccine Handling: Operational Considerations for Healthcare Practitioners

Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
EUA	Issued December 11, 2020	Issued December 18, 2020	Issued February 27, 2021
Fact sheet	Health care providers	Health care providers	Health care providers
	Recipients/caregivers	 Recipients/caregivers 	 Recipients/caregivers
	Interim recommendation for use:	Interim recommendation for use:	Interim recommendation for use:
ACIP	Persons aged ≥12 years for prevention of COVID-19	Persons aged ≥18 years for prevention of COVID-19	Persons aged ≥18 years for prevention of COVID-19
CDC resources	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Janssen COVID-19 Vaccine
CDC clinical considerations		Interim Clinical Considerations	





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
Dosing and Administration			
Vaccine type	mRNA		Viral Vector
Administer	Intramuscular (I.M.)		
Dose	30 mcg (0.3 mL each)	100 mcg (0.5 mL each)	5x10 ¹⁰ viral particles (0.5 mL each)
Doses per vial	6	10-11 dose vial or 13-15 dose vial	5
Schedule	Two-dose series	Two-dose series	Single dose
Recommended interval	21 days from first dose	28 days from first dose	N/A
Earliest interval	17 days from first dose	24 days from first dose	N/A
Latest interval	42 days from first dose		N/A
Administration Errors	Refer to CDC's COVID-19 Vaccine Administration Errors of Deviations guide for information about how to handle these situations.		





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
Storage*			
How product arrives	Frozen liquid. No preservative.		Liquid suspension. No preservative.
Long-term storage	Ultra-low freezing until expiry date OR store frozen between -25°C to -15°C (-13°F to 5°F) for up to 2 weeks	Store frozen between -50°C to -15°C (-58°F to 5°F) until expiry date	Refrigerate until expiry date
Thawing	Thaw in refrigerator for at least 2–3 hours or at room temperature; must be at room temperature for at least 30 mins before dilution; do NOT refreeze	Thaw in refrigerator for at least 2–3 hours or at room temperature; must be at room temperature for at least 30 mins before administration; do NOT refreeze	Product is stored frozen by manufacturer until shipped at refrigerated temperatures; If vaccine is still frozen upon receipt, thaw at refrigerated temperature or if immediate use is required, thaw at room temperature; do NOT refreeze
Max time refrigerated unpunctured	30 days	30 days	Until expiry date
Max time at room temperature unpunctured	2 hours	24 hours	12 hours

*Temperature Key:

- Ultra-low Frozen Temperature: -80°C to -60°C (-112°F to 76°F)
- Pfizer-BioNTech Frozen Temperature: -25°C to -15°C (-13°F to 5°F)
- Moderna Frozen Temperature: -50°C to -15°C (-58°F to 5°F)
- Refrigerated Temperature: 2°C to 8°C (36°F to 46°F)
- Room Temperature: 9°C to 25°C (47°F to 77°F)





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Dose Preparation			
Dilution	Dilute with 1.8 mL of 0.9% sodium chloride (normal saline, preservative free).	Not c	liluted.
Coloring	Off-white	suspension	Colorless to slightly yellow, clear very opalescent suspension
Handling	Do NOT shake; invert only	Do NOT shake; swirl t	pefore drawing up dose
Max time refrigerated after first punctured	6 hours after dilution	12 hours	6 hours
Max time at room temperature after first punctured	6 hours after dilution	12 hours	2 hours
Efficacy and Safety Informa	ation		
Publications	Dagan, et al. NEJM. Feb 24, 2021 Polack, et al. NEJM. Dec 31, 2020 Walsh, et al. NEJM. Dec 17, 2020	Baden, et al. NEJM. Feb 4, 2021 Anderson, et al. NEJM. Dec 17, 2020 Jackson, et al. NEJM. Nov 12, 2020	Sadoff, et al. NEJM. Jan 13, 2021
Overall efficacy; prevention of COVID-19 infection	95% beginning 7 days after second dose: <u>primary analysis</u> of Phase III trial data in 43,538 volunteers	94% beginning 14 days after second dose: <u>primary analysis</u> of Phase III trial data in >30,000 volunteers	67% beginning 14 days after single dose: primary analysis of Phase III trial data in >40,000 volunteers
Prevention of severe COVID-19 infection	89%	100%	85%
Prevention of asymptomatic COVID-19 infection	Under evaluation	Limited data suggest some degree of prevention	Data suggest a 60% reduction in asymptomatic infection from 29 days after dose





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
Efficacy and Safety Informa	tion (continued)		
Study demographics	26.2% Hispanic/Latino; 9.8% African American; 4.4% Asian; <3% other races/ ethnicities Age and sex distribution: 50.6% male;	Diversity of volunteers: 79.4% White; 20% Hispanic/Latino; 9.7% African American; 4.7% Asian; <3% other races/ ethnicities Age and sex distribution: 52.6% male; 47.4% female; 25.3% 65 years and older	Diversity of volunteers: 59% White; 45% Hispanic/Latino; 19% African American; 3% Asian; 9% Native American Age and sex distribution: 55% male; 45% female; 34% 60 years and older
Patient Counseling	 Injection site: Pain, swelling, erythemallymphadenopathy (80%–89% of vaccing vaccinated persons*; acetaminophen of vaccinated persons*; acetaminophen of these symptoms tend to be more compresolve 1–3 days after vaccination Anaphylaxis following vaccination is not at a rate of 4.7 cases/million for Pfizer cases/million for Moderna as of 1/18/of vaccination outweighs risk of anaphylaxis Access a comprehensive summary of adverse events, and serious adverse excovided and serio	nated persons*) nills, myalgia, arthralgia (55%–83% of or ibuprofen may be used) nmon after the second dose and noted in US postmarket surveillance r-BioNTech and at a rate of 2.5 //21; unless contraindicated, benefit hylaxis; refer to CDC's guidance on local reactions, systemic reactions, events for the Pfizer or Moderna	 Injection site: Pain, swelling, erythema Systemic: Headache, fatigue, muscle ache, nausea, fever Warn about the rare potential onset of symptoms of thrombocytopenia syndrome (TTS) 1–2 weeks after vaccination, including shortness of breath, chest pain, leg swelling, abdominal pain, persistent headache, or bruising around injection site. Access a comprehensive summary for the Janssen COVID-19 vaccine.





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
Efficacy and Safety Informa	ation (continued)		
Contraindications	 Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to polyethylene glycol [PEG]) have a precaution to Janssen COVID-19 vaccine, and vice versa Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines Immediate (within 4 hours) allergic reaction of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine (see ingredients below) Persons with contraindication to one mRNA vaccine should not receive doses of either mRNA vaccine 		
Precautions	 Among persons without a contraindice vaccines or injectable therapies Persons with a contraindication to m Janssen COVID-19 vaccine, and vice 	on, do not vaccinate and consider referral cation, a history of any immediate (within RNA COVID-19 vaccines (Pfizer-BioNTech versa	4 hours) allergic reaction to other or Moderna) have a precaution to





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)	
Clinical Considerations				
Interchangeability of COVID-19 vaccines	COVID-19 vaccines are not interchangeable; if the first dose of an mRNA COVID-19 vaccine was received, but the patient is unable to complete the series (e.g., contraindication), then the Janssen COVID-19 vaccine may be given at a minimum interval of 28 days from mRNA dose and the patient is considered to have received a valid, single-dose Janssen vaccination, not a mixed vaccination series			
Coadministration with other vaccines	May be administered without regard to timing; it is unknown whether coadministration with other vaccines increases reactogenicity of the COVID-19 vaccine; providers should consider the benefits and risks of coadministration when deciding whether to coadminister other vaccines within 14 days of COVID-19 vaccination			
Coadministration with antipyretic/analgesic	Prophylactic administration of antipyretic or analgesic medications for the prevention of postvaccination symptoms is NOT recommended; these medications may be used if postvaccination symptoms occur, and patient need exists			
Persons with a history of SARS-CoV-2 infection	Vaccination should be offered regardless of prior SARS-CoV-2 infection; while vaccine supplies remain limited, persons with a history of infection may choose to delay vaccination, if desired			
Persons with a history of MIS-C or MIS-A	There is no data on the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A); access more information on the risks and benefits			
Persons treated with antibodies	Persons who received antibody therapy for COVID-19 should defer vaccination for 90 days			
Considerations for the Use of	f the Janssen COVID-19 Vaccine			
Women aged < 50 years	These persons may receive the vaccine but should be made aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines.			
Persons with a history/risk for thrombosis	Persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT), should avoid the use of the Janssen COVID-19 vaccine; persons with a history or risk of venous thromboembolism are not believed to be more susceptible to TTS.			
Use of aspirin or anticoagulants	Persons who take these medications do not need to stop taking them prior to receiving the Janssen COVID-19 vaccine; it is not recommended to begin taking these medications prior to receiving this vaccine.			





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Special Populations				
Immunocompromised persons	May be vaccinated; safety and efficacy data limited; counsel on the potential for a reduced immune response to the vaccine (efficacy) and the need to follow current guidance to protect themselves against COVID-19 (e.g., masks, social distancing); antiviral therapy is unlikely to impact development of a protective antibody response			
Persons with autoimmune disorder	May be vaccinated; no safety and efficacy data available, but persons with autoimmune disorders were included in clinical trials			
Pregnant/lactating women	May be vaccinated; pregnant or breastfeeding women were not included in the clinical trials; postauthorization <u>safety</u> <u>monitoring</u> of >30,000 women has not revealed a safety problem; mRNA and viral vector COVID-19 vaccines are not considered live virus vaccines and are not considered a risk to the breastfeeding infant			
Children and adolescents	Children and adolescents ages 12-17 years are eligible for vaccination; this age group may be at increased risk of syncope after any vaccine, including COVID-19	Not recommended to persons ≤18 years of age	Not recommended to persons ≤18 years of age	
Other populations	Persons with a history of Guillain-Barre syndrome or Bell's palsy may be vaccinated; persons with a history of dermal filler use may experience temporary swelling at or near the site of filler injection following vaccination and should follow up with their health care provider if this occurs			





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Ingredients			
Ingredients	 Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 2[(polyethylene glycol)*-2000]-N,N-ditetradecylacetamide 1,2-distearoyl-sn-glycero-3-phosphocholine Cholesterol (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) Potassium chloride Monobasic potassium phosphate Sodium chloride Dibasic sodium phosphate dihydrate 	 Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 Polyethylene glycol (PEG)* 2000 dimyristoyl glycerol (DMG) 1,2-distearoyl-sn-glycero-3-phosphocholine Cholesterol SM-102 (proprietary to Moderna) Tromethamine Tromethamine hydrochloride Acetic acid Sodium acetate Sucrose 	 5×10¹⁰ virus particles Citric acid Trisodium citrate Ethanol 2-hydroxypropyl-β-cyclodextrin Polysorbate-80* Sodium chloride

^{*}As of March 1, 2021, mRNA COVID-19 vaccines are the only vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information can be found in CDC's vaccine excipient summary).

Disclaimer: Information related to the COVID-19 pandemic is changing rapidly and continuously. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.

