

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>VaxText<sup>SM</sup> 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
raci sneet	Recipients/caregivers	Recipients/caregivers	Recipients/caregivers
ACIP	Interim recommendation for use: Persons aged ≥12 years for prevention of COVID-19	Interim recommendation for use: Persons aged ≥18 years for prevention of COVID-19	Interim recommendation for use: 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	m	RNA	Viral Vector
Administer	Intramuscular (I.M.)		
Dose	30 mcg ( <b>0.3 mL each</b> )	100 mcg ( <b>0.5 mL each</b> )	5x10 <sup>10</sup> viral particles ( <b>0.5 mL each</b> )
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)





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
Dose Preparation			
Dilution	Dilute with 1.8 mL of 0.9% sodium chloride (normal saline, preservative free).	Not diluted.	
Coloring	Off-white	suspension Colorless to slightly yellow, clear ver opalescent suspension	
Handling	Do NOT shake; invert only	Do NOT shake; swirl before 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 Inform	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	<b>95%</b> beginning 7 days after second dose: primary analysis of Phase III trial data in 43,538 volunteers	<b>94%</b> beginning 14 days after second dose: primary analysis of Phase III trial data in >30,000 volunteers	<b>67%</b> beginning 14 days after single dose: <u>primary analysis</u> 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 Inform	Efficacy and Safety Information (continued)				
Study demographics	Diversity of volunteers: 81.9% White; 26.2% Hispanic/Latino; 9.8% African American; 4.4% Asian; <3% other races/ethnicities  Age and sex distribution: 50.6% male; 49.4% female; 21.4% 65 years and older	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	Age and sex distribution, 52.0% male,		<ul> <li>Injection site: Pain, swelling, erythema</li> <li>Systemic: Headache, fatigue, muscle ache, nausea, fever</li> <li>Warn about the <u>rare</u> 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.</li> <li>Access a comprehensive summary for the <u>Janssen</u> COVID-19 vaccine.</li> </ul>		





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)		
Efficacy and Safety Info	Efficacy and Safety Information (continued)				
Contraindications	Severe allergic reaction (e.g., anaphylax	Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine			
	<ul> <li>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</li> </ul>				
	<ul> <li>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</li> </ul>				
	• 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)				
	<ul> <li>Persons with contraindication to one mRNA vaccine should not receive doses of either mRNA vaccine (Pfizer-BioNTech or Moderna)</li> <li>If screen positive for a contraindication, do not vaccinate and consider referral to allergist-immunologist</li> </ul>				
Precautions	<ul> <li>Among persons without a contraindication, a history of any immediate (within 4 hours) allergic reaction to vaccines or injectable therapies</li> </ul>		hours) allergic reaction to other		
	<ul> <li>Persons with a contraindication to mRNA COVID-19 vaccines (Pfizer-BioNTech or Moderna) have a precautic Janssen COVID-19 vaccine, and vice versa</li> </ul>				
If screen positive for a precaution, complete a risk assessment, consider referral to allergist-observe for 30 minutes postvaccination		to allergist-immunologist, and			





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)		
Clinical Considerations	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 co-administer 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 o	Considerations for the Use of 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.				





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)	
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; symptoms of myocarditis and pericarditis have been reported after vaccination  Not recommended to persons ≤18 years of age  ≤18 years of age			
Other populations	Persons with a history of Guillain-Barre sy	rndrome or Bell's palsy may be vaccinated; penear the site of filler injection following vacci		





Vaccine	Pfizer-BioNTech (BNT162b2)	Moderna (mRNA-1273)	Janssen (Ad26.CoV2.S)
Ingredients			
	<ul> <li>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</li> </ul>	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized
	<ul> <li>2[(polyethylene glycol)*-2000]-N,N- ditetradecylacetamide</li> </ul>	Polyethylene glycol (PEG)* 2000 dimyristoyl glycerol (DMG)	variant of the SARS-CoV-2 Spike (S) protein
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	Citric acid
	Cholesterol	• Cholesterol	Trisodium citrate
	• (4-hydroxybutyl)azanediyl)bis(hexane-6,1-	SM-102 (proprietary to Moderna)	Ethanol
	diyl)bis(2-hexyldecanoate)	Tromethamine	2-hydroxypropyl-β-cyclodextrin
	Potassium chloride	Tromethamine hydrochloride	Polysorbate-80*
	Monobasic potassium phosphate	Acetic acid	Sodium chloride
	Sodium chloride	Sodium acetate	
	Dibasic sodium phosphate dihydrate	• Sucrose	
	Sucrose		

<sup>\*</sup>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 <u>vaccine excipient summary</u>).

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.

