COVID-19 Vaccines

(Updated January 8, 2021)

The chart below provides dosing, storage, adverse effects, and efficacy information for COVID-19 vaccines available or submitted for approval in the U.S. and/or Canada. The American Society of Health System Pharmacists has resources related to COVID-19 vaccines at https://www.ashp.org/COVID-19/Vaccines?loginreturnUrl=SSOCheckOnly. See end of chart for links to the **fact sheets** and **product labelling**.

Vaccine/ Type/Status	Dosing	Storage/Stability[e]	Adverse Effects	Efficacy[d]
BNT162b2 (Pfizer-BioNTech)/ mRNA U.S.: Emergency Use Authorization Canada: authorized by interim order.	Two 0.3 mL doses (0, 21 days) IM for ≥16 years of age[18,19] Requires dilution with 1.8 mL of NS per vial.[18,19]	Special dry ice shipper:[b] ≤15 days from receipt (undiluted)[7] Ultracold freezer (-70ºC±10ºC): ≤6 months (undiluted)[7] Thawing (required before diluting): may take two to three hours in the refrigerator,[18,19] or 30 minutes at room temperature.[19] Allow vial to reach room temperature before diluting.[19] Do not refreeze.[18,19] Refrigerator (2ºC to 8ºC): 5 days undiluted; 6 hours once diluted[18,19] Room Temp (up to 25ºC): 2 hours, undiluted, 6 hours once diluted, minimizing light exposure[18,19]	• Most (>95%) adverse effects were mild to moderate.[5] • **Local/injection site**: mild to moderate pain in >65% of patients. Severe pain in <1%. Redness and swelling much less common.[5] • **Systemic**: fatigue (<60%), headache (≤52%), myalgia (≤37%), chills (≤35%), arthralgia (≤22%), fever ≥38ºC (≤16%).[5] Less common: diarrhea (<11%), vomiting.[17] Any **severe** event after first dose ≤0.9%, and <2% after the second dose, except fatigue (3.8%) and headache (2%).[5] • Recipients can expect local adverse effects to resolve within one to two days.[5] Systemic effects occur within the first one to two days, then resolve quickly.[5] Participants were allowed to use analgesics/antipyretics.[5] • Appears better tolerated in older (>55 years of age) vs younger adults.[5] • Four cases of Bell's palsy occurred in the vaccine group.[17] • Severe allergic reactions have been reported outside of clinical trials.[19] Treatment for severe allergic reactions must be immediately available.[19]	• 54.2% effective between dose one and two, starting ~**14 days after the first dose**.[17] • 95% effective (95% CI 90.3% to 97.6%) **seven days after the second dose** (n=43,448).[5] NNV =71. 94.7% effective in adults ≥65 years of age.[5] • One severe COVID-19 case (nonhospitalized) in the vaccine group vs nine in the placebo group.[17] • Immunocompromised patients were excluded from trials.[5] • Approval in 16- and 17-year-olds was extrapolated from data in adults, but safety data (n=103) was reviewed.[19] Pediatric studies ongoing.[19] • Immunogenicity (Phase I study):[a] produced neutralizing antibody response ≥natural infection in adults 18 to 85 years of age.[1]

Vaccine/ Type/Status	Dosing	Storage/Stability[e]	Adverse Effects	Efficacy[d]
mRNA-1273 (Moderna)/ mRNA U.S.: Emergency Use Authorization Canada: authorized by interim order	Two 0.5 mL doses (0, 1 month) IM for ≥18 years of age[21,22] Does not require dilution.[21,22]	Shipping and long-term storage: -25ºC to -15ºC for ≤6 months[6] Refrigerator (2ºC to 8ºC): 30 days after thawing (prior to first use), within the 6-month shelf-life[6,21,22] Room temperature: 12 hours (6 hours after the first dose is withdrawn)[21,22]	• >90% of adverse effects mild to moderate.[4] • **Local/injection site**: mild to moderate pain in >80% of patients. **Severe** pain in 2.8% of patients after the first dose and in 4.1% after the second dose.[4] • **Systemic**: fatigue (68.5%), headache (63%), myalgia (59.6%), chills (43.4%), arthralgia (44.8%), fever (14.8%). Less common: nausea, vomiting, diarrhea. **Severe** adverse events after 2nd dose: fatigue (9.7%), myalgia (8.6%), arthralgia (5.1%), headache (5.5%).[4] • Median duration of adverse effects was two days (three for local effects after 2nd dose).[4] Participants were allowed to use analgesics/antipyretics.[4] • Appears better tolerated in older (≥65 years of age) vs younger patients.[4] • Three cases of Bell's palsy occurred in the vaccine group, one in the placebo group.[4]	• 92.1% effective between dose one and two, starting **~14 days after the first dose**.[4] Protection beyond 28 days after a single dose unknown.[4] • 94.1% effective (95% CI 89.3% to 96.8%) **14 days after second dose** (n=27,817).[4] NNV = 80. No cases of severe COVID-19 in the vaccine group vs 11 in the placebo group.[4] • ~25% of patients were ≥65 years of age, 9.4% had diabetes, ~6.5% had severe obesity, ~5% had significant heart disease, and ~5% had chronic lung disease.[4] • Immunogenicity (Phase I study):[a] produced neutralizing antibody response in adults comparable to natural infection, even in patients >70 years of age.[2,13] Minimal Th2 response.[2,13]

AZD1222 (AstraZeneca)/ Viral vector (non-replicating)
 	
Phase III data published.
 	
Canada: approval pending
	Two doses IM (0, 28 days)[3,8]	Refrigerator (2ºC to 8ºC) for ≤6 months[9]	• Meningococcal conjugate (MenACWY) vaccine used as comparator to maintain blinding in regard to adverse effects.[3]
			• Transverse myelitis occurred in three patients (one placebo). A possible vaccine relationship was not ruled out in one case.[20]
			• **Local/injection site** (Phase II/III study): pain and tenderness occurred most often.[15]
			• **Systemic** (Phase II/III study): occurred in most patients. Fatigue, headache, feverishness, and myalgia.[15] Other systemic side effects were malaise and chills. Few patients had objectively documented fever.[15]
			• Better tolerated in older patients.[15]
			• Adverse effects peaked day after vaccination.[3]
				• Interim analysis of Phase I-III data:
				  • Half dose,[c] followed by full dose (n=2,741): 90% (≥14 days after second dose)[20]
				  • Two full doses (n=8,895): 62.1% (≥14 days after second dose)[20]
				  • Combined results: 70.4% effective[20]
				  • No cases of severe COVID-19 occurred in the COVID-19 vaccine group.[20]
				• Immunogenicity:[a] produced neutralizing antibody response in adults 18 to ≥70 years of age.[15] Immunogenicity was not affected by acetaminophen.[3]

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Vaccine/ Type/Status	Dosing	Storage/Stability[e]	Adverse Effects	Efficacy[d]
JNJ-78436735 Johnson & Johnson/ Viral vector (non-replicating) Phase III underway[14] Canada: approval pending	One IM dose[8,10] (two-dose regimen also being studied)	2 years at -20ºC and at least 3 months at 2ºC to 8ºC[11]	Phase I/IIa data: • Most adverse effects were mild to moderate.[10] • **Local/injection site**: occurred in 58% of patients 18 to 55 years of age, and in 27% of patients ≥65 years of age, most commonly injection site pain.[10] A few patients reported severe pain, swelling, or tenderness.[10] • **Systemic**: occurred in 64% of patients 18 to 55 years of age, and in 36% of patients ≥65 years of age, most commonly fatigue, headache, and myalgia.[10] Fever occurred in <20% of patients within two days of immunization but resolved within one to two days.[10]	• Immunogenicity (Phase I/IIa study):[a] Produced neutralizing antibody response comparable to natural infection in 98% of adults 18 to 55 years of age, and 100% of adults 65 to 75 years of age.[10] No or minimal Th2 response.[10] Robust CD8+ response.[10]

a. Neutralizing antibodies and Th1 CD4+ polarization are thought to be desirable. Neutralizing antibodies were associated with protection in non-human primate studies. Th1 polarization means that there is more of a response by Th1 CD4+ helper T cells than Th2 CD4+ helper T cells. Th2>Th1 response was associated with immunopathologic lung damage ("enhanced respiratory disease") in preclinical SARS-CoV-1 and MERS vaccine studies.[12]

b. Pfizer unpackaging and re-icing instructions for the special shipper: https://dhhr.wv.gov/COVID-19/Documents/Pfizer%20Unpackaging%20and%20Re-Icing%20Parcel%20Shipper.pdf.

c. Half-dose used due to manufacturing error.[16]

d. **Efficacy** = Based on reduction of documented COVID-19 infections (COVID-19 symptoms plus confirmatory test for SARS-CoV2 test [polymerase chain reaction]).[17,19,20] This means we do not know if the vaccine prevents asymptomatic infection.

e. **USP**: Vaccines should be prepared in accordance with the manufacturer's labeling. This means that USP engineering controls, risk levels, and beyond-use dating is not required. See https://www.usp.org/compounding.

Abbreviations: IM = intramuscular; NS = normal saline

Fact Sheets and Product Labeling

- Pfizer-BioNTech vaccine EUA fact sheet for healthcare professionals (U.S.): https://www.fda.gov/media/144413/download
- Pfizer-BioNTech vaccine EUA fact sheet for patients (U.S.): https://www.fda.gov/media/144414/download
- Pfizer-BioNTech vaccine Canadian product monograph/patient information: https://pdf.hres.ca/dpd_pm/00059220.PDF
- Moderna vaccine EUA fact sheet for healthcare professionals (U.S.): https://www.fda.gov/media/144637/download
- Moderna vaccine EUA fact sheet for patients (U.S.): https://www.fda.gov/media/144638/download
- Moderna vaccine Canadian product monograph/patient information: https://pdf.hres.ca/dpd_pm/00059305.PDF

Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

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