COVID-19 Vaccines

(Updated March 31, 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 labeling**.

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. *Continued…*	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**: see **footnote b** for storage/handling Ultracold freezer (-70ºC±10ºC): Mfr expiration date (undiluted)[19] Freezer (-20ºC±5ºC): ≤2 weeks.[19] **Thawing** (required before diluting): may take ~two to three hours in the refrigerator, or 30 minutes at room temperature. Allow vial to reach room temperature before diluting. Do not refreeze.[18,19] **Refrigerator** (2ºC to 8ºC): 5 days undiluted; 6 hours once diluted (vial or pre-drawn syringe)[18,19,32] **Room Temp** (up to 25ºC): 2 hours, undiluted, 6 hours once	• 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] • Anaphylaxis reported.[18,19] • **Lymphadenopathy** (16%) may interfere with imaging (e.g., mammography) for four to six weeks after vaccination.[35]	• 54.2% effective between dose one and two, starting ~**14 days after the first dose**.[17] Israeli data suggests a 33% reduction in positive COVID tests (as opposed to symptomatic disease) in those ≥60 years of age.[26] • 80% reduction in hospitalization after one dose in age >80 years (U.K. data).[33] • 95% effective (95% CI 90.3% to 97.6%) **seven days after the second dose** (n=43,448).[5] NNV[f] = 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 (88.9% effective after first dose).[17] • Immunocompromised patients were excluded from trials.[5] • Pediatric studies ongoing.[17] • *In vitro* data suggest efficacy against the new UK and South African variants.[27-28] • 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]
Pfizer vaccine, continued		diluted (vial or pre-drawn syringe), minimizing light exposure[18,19,32]		
mRNA-1273 (Moderna)/ mRNA U.S.: Emergency Use Authorization Canada: authorized by interim order	Two 0.5 mL doses (0, 1 month [days 26 to 36]) IM for ≥18 years of age[21-23] Does not require dilution.[21,22]	**Shipping and long-term storage**: -25°C to -15°C until mfr expiration date[6] **Refrigerator** (2°C to 8°C): 30 days after thawing (prior to first use). After 30 days, contact manufacturer for guidance before discarding.[6] In-use vial/pre-drawn syringe: 6 hours[6,32] **Room temperature** (8°C to 25°C): Unused vial: 12 hours; In-use vial/pre-drawn syringe: 6 hours[21,22,32]	• >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%).[4] 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] • Anaphylaxis reported.[22,36] • **Lymphadenopathy** (16%) may interfere with imaging (e.g., mammography) for four to six weeks.[35] • **Delayed-type hypersensitivity reaction** (e.g., large, red area near injection site about a week after shot) is not a contraindication to subsequent vaccination.[37] May be itchy, painful, warm, or swollen, and can also involve fingers, elbow, or palm. More common with first shot.[37]	• 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[f] = 80. No cases of severe COVID-19 in the vaccine group vs 30 in the placebo group (starting 14 days after the 2nd dose).[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] • *In vitro* data suggest efficacy against the new UK and South African variants, but efficacy against the South African variant might wane.[24,25] Use of a third dose (of the same vaccine, or a new one modified to target this variant) is being studied.[24] • 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]

Vaccine/ Type/Status	Dosing	Storage/Stability[e]	Adverse Effects	Efficacy[d]
Ad26.COV2.S Janssen (J&J)/ Viral vector (non-replicating) U.S.: Emergency Use Authorization Canada: authorized by interim order	One 0.5 mL IM dose for ≥18 years of age[9,31] (two-dose regimen also being studied)	If arrives frozen, refrigerate, or for immediate use, thaw at room temperature (max 25ºC). May take 2 hours to thaw.[9] **Refrigerator** (2ºC to 8ºC): Mfr expiration date (unused vial);[11,31] In-use vial/pre-drawn syringe: 6 hrs.[11,31,32] **Room temperature** (9ºC to 25ºC): Unused vial: 12 hours. In-use vial/pre-drawn syringe: 2 hours (Canada: 3 hours)[11,31,32]	Phase III data:[9] • Most adverse effects were mild to moderate.[9] • **Local/injection site**: occurred in 58.6% of patients 18 to 59 years of age, and in 33.3% of patients ≥65 years of age, most commonly injection site pain.[9] <1% were severe.[9] **Systemic**: most commonly headache (30.4% to 44.4%), fatigue (29.7% to 43.8%), and myalgia (24% to 39.1%), with better tolerability in patients ≥65 years of age.[9] Other adverse effects included fever and nausea.[9] • Anaphylaxis reported.[9,31]	• For preventing moderate to severe/critical COVID-19 disease 28 days post-vaccination, efficacy was 72% in the U.S., 68.1% in Brazil, and 64% in South Africa (n=29,371).[9] There were no COVID-19 deaths in the vaccine group.[9] Overall, it was 85.4% effective for preventing severe/critical COVID-19.[9] • Immunogenicity (Phase I/IIa study):[a] Produced neutralizing antibody response in >95% of patients.[10] No or minimal Th2 response.[10] Robust CD8+ response.[10]

ChAdOx1-S* (**AstraZeneca**)/ Viral vector (non-replicating)
Phase III data published.
Canada: authorized by interim order
*Canada: also manufactured by Serum Institute of India (*Covishield*)
	Two 0.5 mL doses (0 and 4 to 12 weeks) IM for ≥18 years of age[8,30]	**Refrigerator** (2ºC to 8ºC): Mfr expiration date (unused vial); 48 hours (punctured vial)[8,30]
		
		Room temperature (≤30ºC): 6 hours (punctured vial). Vial can be re-refrigerated, but the cumulative storage at room temperature cannot exceed 6 hours, and the total cumulative storage time cannot exceed 48 hours[8,30]
			• 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, most commonly fatigue, headache, feverishness, and myalgia.[15] Other systemic side effects were malaise and chills. Few patients had confirmed fever.[15] Better tolerated in older patients.[15] Adverse effects peaked day after vaccination.[3]
			• Current evidence does not suggest thrombosis risk, except cerebral sinus vein thrombosis with low platelets (rare; 1 in 250,000 to 500,000).[34]
			• Anaphylaxis reported.[37]
				• Among patients who received two full doses[c] 4 to 12 week apart, in the UK and Brazil (n=10,468):[8,30]
				  • 59.5% effective ≥15 days after second dose)[8,30]
				  • No cases of severe COVID-19 occurred in the COVID-19 vaccine group.[8,30]
				  • Limited data in patients ≥65 years.[8,30]
				• Efficacy better with 12-week interval.[8,30]
				• 80% reduction in hospitalization after one dose in age >80 years (UK data).[33]
				• Immunogenicity:[a] produced neutralizing antibody response in adults 18 to ≥70 years of age.[15] Immunogenicity was not affected by acetaminophen.[3]

Vaccine/ Type/Status	Dosing	Storage/Stability[e]	Adverse Effects	Efficacy[d]
NVX-CoV2373 (Novavax)/ Protein subunit, adjuvanted Phase III; rolling review process in U.S. and Canada[14]	Two doses IM (0, 21 to 28 days)[7]	**Refrigerator** (2°C to 8°C)[7]	• Occurred in most patients, especially after the second dose. Mean duration was ≤2 days.[29] • **Local/injection site** (Phase I/IIa study): pain and tenderness (mild to moderate) occurred most often.[29] • **Systemic** (Phase I/IIa study): headache, fatigue, and myalgia occurred most often. A few patients experienced severe adverse effects (fatigue, myalgia, arthralgia) after the second dose. Other systemic side effects were nausea and malaise.[29]	• In UK, 89.3% effective overall, and 95.6% effective against original strain.[14] Up to 60% effective against South African variants.[14] • Immunogenicity (Phase I/IIa study):[a] Produced neutralizing antibody response similar to convalescent hospitalized patients. Minimal Th2 response.[29]

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 vaccine storage and dry ice safety handling resources at https://www.cvdvaccine-us.com/product-storage-and-dry-ice.
c. Some other patients in the studies received only a half-dose for the first dose due to manufacturing error.[16,20]
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.
f. **NNV** is the number needed to vaccinate to prevent one symptomatic case.

Abbreviations: IM = intramuscular; NS = normal saline; UK = United Kingdom

The CDC has interim recommendations for **COVID-19 vaccine administration errors and deviations** available at https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-errors-deviations-poster.pdf.

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
- Janssen (J&J) vaccine EUA fact sheet for healthcare professionals (U.S.): https://www.fda.gov/media/146304/download
- Janssen (J&J) vaccine fact sheet for patients (U.S.): https://www.fda.gov/media/146305/download
- Janssen (J&J) vaccine Canadian product monograph/patient information: https://pdf.hres.ca/dpd_pm/00060088.PDF
- AstraZeneca vaccine Canadian product monograph/patient information: https://pdf.hres.ca/dpd_pm/00060240.PDF
- *Covishield* (AstraZeneca vaccine made by Verity Pharmaceuticals) Canadian product monograph/patient information: https://pdf.hres.ca/dpd_pm/00060285.PDF

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