

WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

WHO recommendation Serum Institute of India Pvt Ltd - COVID-19 Vaccine (ChAdOx1-S [recombinant]) - COVISHIELD™

	Product Overview		
Vaccine type:	COVID-19 Vaccine (ChAdOx1-S ([recombinant])		
Commercial name:	COVISHIELD™		
Manufacturer:	Serum Institute of India Pvt. Ltd		
Country:	India		
URL:	https://www.seruminstitute.com/ [https://www.seruminstitute.com/]		
Responsible NRA:	Central Drugs Standard Control Organization		
Country:	India		
URL:	https://cdsco.gov.in/opencms/opencms/en/Home/ [https://cdsco.gov.in/opencms/opencms/en/Home/]		
	WHO Recommendation		
Effective date:	15 February 2021		
	Product Description		
Pharmaceutical form:	Solution for injection		
Presentation:	Vial		
Number of doses:	2 and 10 doses		
Diluent:	Not applicable		
Route of administration	Intramuscular		
Shelf-life:	6 months	at storage temperature:	2°C to 8°C
Vaccine vial monitor:	None		
Secondary packaging:	COVIDSHIELD-2dose: Carton holds 50 vaccine vials (100 doses) Dimensions: 18.5 x 9.5 x 4.0 cm COVIDSHIELD-10 dose: Carton holds 50 vaccine vials (500 doses) Dimensions: 18.5 x 9.5 x 6.0 cm		

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Tertiary packaging:	COVIDSHIELD-2dose: 6 secondary packaged cartons containing 50 vials per carton (300 vials /600 doses): Dimensions: 31.0 x 19.0 x 9.3 cm		
	COVIDSHIELD-10 dose: 6 secondary packaged cartons containing 50 vials per carton (300 vials /3000 doses): Dimensions: 31.0 x 19.0 x 9.3 cm		
Cold chain volume:	7.03 (2 dose vial) 2.109 (10 dose vial)	cm3 (in secondary packaging)	
Preservative:	Not applicable	with concentration:	Not applicable
Handling of opened multidose-vials:	WHO recommends that opened vials of this vaccine should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.		

WHO RECOMMENDATION

WHO Recommendation for EUL of COVISHIELD™ submitted by Serum Institute of India Pvt Ltd (Published: 26 February 2021) [/pqweb/key-resources/documents/who-recommendation-eul-covishield-submitted-serum-institute-india]

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