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

## WHO recommendation Janssen-Cilag International NV (Belgium) COVID-19 Vaccine (Ad26.COV2-S [recombinant])

	<b>Product Overview</b>		
Vaccine Type:	COVID-19 Vaccine (Ad26.COV2-S [recombinant])		
Commercial Name:	Not Applicable		
Manufacturer:	Janssen-Cilag International NV		
Country:	Belgium		
URL:	https://www.janssen.com/belgium/ [https://www.janssen.com/belgium/]		
Responsible NRA:	European Medicines Agency		
Country:	The Netherlands		
URL:	https://www.ema.europa.eu/en [https://www.ema.europa.eu/en]		
	WHO Recommendation		
Effective date:	12/03/2021		
	<b>Product Description</b>		
Pharmaceutical Form:	Suspension for injection		
Presentation:	vial		
Number of Doses:	5 doses		
Diluent:	Not applicable		
Route of administration:	Intramuscular		
Shelf Life:	24 months	at storage temperature:	-25°C to -15°C
Special conditions storage:	Within the 24 months of shelf life the vaccine can be stored 3 months at 2°C to 8°C		
Vaccine Vial Monitor:	None		
Secondary Packaging:	Carton box holds 10 vaccine vials (50 doses) Dimensions: 9.3 x 3.8 x 5.4 cm		
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Tertiary Packaging:	48 secondary packaged cartons containing 10 vials per carton (480 vials/2400 doses): Dimensions: 39.3 x 24.8 x 13.1		
Cold Chain Volume:	3.82	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		

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