



डॉ. मनोहर अगनानी, भा.प्र.से. अपर सचिव

DR. MANOHAR AGNANI, IAS Additional Secretary

भारत सरकार स्वास्थ्य एवं परिवार कल्याण मंत्रालय निर्माण भवन, नई दिल्ली-110011

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

DO No. T-22020/14/2020-Imm Date: 14th January 2021

Dear 411,

As you are aware that COVID-19 vaccine is scheduled for roll-out in the country on 16th Jaunaury 2021 and the States/UTs have already received vaccines for the same.

In this regard, a comparative factsheet for both the vaccines that will be used during the introduction have been prepared which contains information on vaccine platform, physical specifications, dosage, cold chain storage requirements, contraindications and minor AEFIs. A detailend note on contrainidcations and special precautions has also been prepared and is enclosed.

You are requested to kindly disseminate the above mentioned documents to Programme Managers across all levels and through them to cold chain handlers and vaccinators for ready reference.

Yours sincerely,

Enclosure: As above

(Dr. Manohar Agnani)

To.

Additional Chief Secretary/Principal Secretary/Secretary, Health & Family Welfare All States/UTs

Copy to:

- 1. Mission Director, NHM, All States/UTs
- 2. State Immunization Officers, All States/UTs

Room No. 145-A, Nirman Bhawan, New Delhi - 110011 Tel.: 011-23061723, E-mail: as-agnani@gov.in

Precautions and Contraindications for COVID-19 Vaccination

- 1. **Authorized Age Group:** Under the EUA, COVID-19 vaccination is indicated only for 18 years and above.
- 2. **Co-administration of vaccines:** If required, COVID-19 vaccine and other vaccines should be separated by an interval of at least 14 days
- 3. **Interchangeability of COVID-19 Vaccines** is not permitted: Second dose should also be of the same COVID-19 vaccine which was administered as the first dose.

Contraindication

- 1. Persons with history of:
 - Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine
 - Immediate or delayed-onset anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc.
- 2. Pregnancy & Lactation:
 - Pregnant & Lactating women have not been part of any COVID-19 vaccine clinical trial so far. Therefore, women who are pregnant or not sure of their pregnancy; and lactating women should not receive COVID-19 vaccine at this time

Provisional / temporary contraindications: In these conditions, COVID vaccination is to be deferred for 4-8 weeks after recovery

- 1. Persons having active symptoms of SARS-CoV-2 infection.
- 2. SARS-COV-2 patients who have been given anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma
- 3. Acutely unwell and hospitalized (with or without intensive care) patients due to any illness

Special precautions:

Vaccine should be administered with caution in persons with history of any bleeding or coagulation disorder (e.g., clotting factor deficiency, coagulopathy or platelet disorder).

Following conditions are not contraindicated for COVID vaccines

- Persons with a past history of SARS-CoV-2 infection (sero-positivity) and or RT-PCR positive illness
- History of chronic diseases and morbidities (cardiac, neurological, pulmonary, metabolic, renal, malignancies)
- Immuno-deficiency, HIV, patients on immune-suppression due to any condition (the response to the COVID 19 vaccines may be less in these individuals)

Other Important Issues to consider

• Vaccine specific contraindications may apply as the new information becomes available

Comparative Sheet for different Covid-19 vaccines, under Indian Government supply

Indicator	COVISHIELD	COVAXIN			
Type of Vaccine	Recombinant COVID-19 vaccine based on Viral Vector Technology	Whole-Virion Inactivated Corona Viru Vaccine			
No. of doses in each vial	10	20			
Shelf life	6 months	6 months			
Expiry date available on vial	Yes	Yes			
Vaccine Vial Monitor (VVM)	Not Available	Not Available			
Route	Intramuscular (IM) Injectable	Intramuscular (IM) Injectable			
Physical Appearance of	Clear to slightly opaque, colourless	Whitish translucent			
Vaccine	to slightly brown				
Dose	0.5 ml each dose	0.5 ml each dose			
Course	2-doses	2-doses			
Schedule	4-weeks apart	4-weeks apart			
Vaccination during Pregnancy	Not recommended	Not recommended			
Vaccination < 18 years of age	Not recommended	Not recommended			
Vaccination to Lactating mother	Not recommended	Not recommended			
Storage and transportation	$+2^{\circ}$ C to $+8^{\circ}$ C at all levels	$+2^{\circ}$ C to $+8^{\circ}$ C at all levels			
Cold chain storage space in	2.109 cm^3	1.7187 cm ³			
secondary packaging	2.107 CH	1.7107 CIII			
Shake test	Not applicable	Not applicable			
Open Vial Policy	Not applicable (Discard after 4 hours of opening)	Not applicable (Discard after 4 hours of opening)			
Freeze Sensitive	Yes	Yes			
Discard the vaccine vial, if found	'frozen' or 'frozen and thawed'	'frozen' or 'frozen and thawed'			
Discard the vial, if	Solution is discoloured or visible particles are observed	Presence of particulate matter or other coloration			
		Some mild AEFIs may occur like injection site pain, headache, fatigue, fever, body			
AEFI	site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and	dizziness-giddiness, tremor, sweating, cold,			
AFRI	arthralgia, nausea	cough and injection site swelling			
AEFI Other	Paracetamol may be used to provide symptomatic relief from post-vaccination adverse reactions				
	Very rare events of demyelinating				
	disorders have been reported				
	following vaccination with this				
	Vaccine without the causal				
	relationship establishment				
	As with other intramuscular				
	injections, COVISHIELD should be				
	given with caution to individuals				
	with thrombocytopenia				
Any other instruction		Shake well, before use			
		Use of Chloroquine and Corticosteroids may impair antibody response.			

Packaging details -

Packaging	Doses		Dimension		Total Volume	
details	COVISHIELD	COVAXIN	COVISHIELD	COVAXIN	COVISHIELD	COVAXIN
Primary	10	20			21.09 cm ³	34.37 cm ³
Secondary	500	320	L-18.5 cm, W-9.5	L- 10 cm, W-	1053 cm ³	550 cm ³
			cm, H- 6 cm	10 cm, H-5.5		
				cm		
Tertiary	3,000	7680	L-31 cm, W-19	L-41 cm, W-	7833 cm ³	14760 cm^3
			cm, H-13.3 cm	20 cm, H- 18		
			,	cm		
Quaternary	12,000	Not	L-57.9 cm, W-	Not Applicable	99402 cm ³	Not
(A)*		Applicable	46.4 cm, H-37cm			Applicable
Quaternary	12,000	Not	L-60 cm, W-48	Not Applicable	$1,18,080 \text{ cm}^3$	Not
(B)		Applicable	cm, H-41cm			Applicable