



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

डॉ. मनोहर अगनानी, भा.प्र.से.  
अपर सचिव

**DR. MANOHAR AGNANI , IAS**  
Additional Secretary

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

*Dear Sir,*

As you are aware that COVID-19 vaccine is scheduled for roll-out in the country on 16<sup>th</sup> Jaunary 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.

Enclosure: As above

*with kind regards,*

Yours sincerely,

*14/01/2021*

(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

## **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**

| <b>Indicator</b>                                       | <b>COVISHIELD</b>   | <b>COVAXIN</b>   |
|--|---|--|
| <b>Type of Vaccine</b>                                 | Recombinant COVID-19 vaccine based on Viral Vector Technology   | Whole-Virion Inactivated Corona Virus Vaccine  |
| <b>No. of doses in each vial</b>                       | 10  | 20   |
| <b>Shelf life</b>                                      | 6 months  | 6 months   |
| <b>Expiry date available on vial</b>                   | Yes   | Yes  |
| <b>Vaccine Vial Monitor (VVM)</b>                      | Not Available   | not available  |
| <b>Route</b>   | Intramuscular (IM) Injectable   | Intramuscular (IM) Injectable  |
| <b>Physical Appearance of Vaccine</b>                  | Clear to slightly opaque, colourless to slightly brown  | Whitish translucent  |
| <b>Dose</b>  | 0.5 ml each dose  | 0.5 ml each dose   |
| <b>Course</b>  | 2-doses   | 2-doses  |
| <b>Schedule</b>  | 4-weeks apart   | 4-weeks apart  |
| <b>Vaccination during Pregnancy</b>                    | Not recommended   | Not recommended  |
| <b>Vaccination &lt; 18 years of age</b>                | Not recommended   | Not recommended  |
| <b>Vaccination to Lactating mother</b>                 | Not recommended   | Not recommended  |
| <b>Storage and transportation</b>                      | +2 <sup>0</sup> C to +8 <sup>0</sup> C at all levels  | +2 <sup>0</sup> C to +8 <sup>0</sup> C at all levels   |
| <b>Cold chain storage space in secondary packaging</b> | 2.109 cm <sup>3</sup>   | 1.7187 cm <sup>3</sup>   |
| <b>Shake test</b>                                      | Not applicable  | Not applicable   |
| <b>Open Vial Policy</b>                                | Not applicable  | Not applicable   |
| <b>Freeze Sensitive</b>                                | Yes   | Yes  |
| <b>Discard the vaccine vial, if found</b>              | 'frozen' or 'frozen and thawed'   | 'frozen' or 'frozen and thawed'  |
| <b>Discard the vial, if</b>                            | Solution is discoloured or visible particles are observed   | Presence of particulate matter or other coloration   |
| <b>AEFI</b>  | Some mild AEFI may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia, nausea   | Some mild AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough and injection site swelling |
| <b>AEFI Other</b>                                      | Paracetamol may be used to provide symptomatic relief from post-vaccination adverse reactions<br><br>Very rare events of demyelinating disorders have been reported following vaccination with this Vaccine without the causal relationship establishment<br><br>As with other intramuscular injections, COVISHIELD should be given with caution to individuals with thrombocytopenia |  |
| <b>Any other instruction</b>                           |   | Shake well, before use<br>Use of Chloroquine and Corticosteroids may impair antibody response.   |

**Packaging details –**

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