

COVID-19 Vaccinations

March 2021

What is Emergency Use Authorization (EUA)/ Permission for restricted use?

- EUA is a regulatory mechanism to allow the **use of vaccines and medicines to prevent and/or reduce the impact of life-threatening diseases** or conditions as caused by COVID-19.
- Before grant of the EUA, rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy is conducted.
- Safety is particularly critical aspect of this scrutiny and a **risk-versus- benefit evaluation is done** in the context of a public health emergency.
- EUA by Indian regulators is aligned with global guidelines.
- Previously, EUAs have been granted to vaccines for outbreaks due to Anthrax, Ebola, Enterovirus, H7N9 Influenza, and Middle East Respiratory Syndrome.

Which vaccine is better between Covishield and Covaxin?

- There is **no head-to-head comparison done** between the two vaccines being used in India so one cannot choose one over the other.
- **Both would work fine in preventing the infection** as well as prevent a person from going into severe state of the disease.
- As a long-term effect, it would be preventing death for elderly people or those who have comorbidities.

Source : www.mohfw.gov.in/covid_vaccination/vaccination/faqs

Expected immediate and delayed side effects of this vaccine?

COVISHIELD®

- Some mild symptoms may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia, nausea.
- Very rare events of demyelinating disorders have been reported following vaccination with this vaccine but without the causal relationship establishment.

COVAXIN®

- Some mild symptoms 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.
- No other vaccine-related serious adverse effects have been reported.

Source : www.mohfw.gov.in/covid_vaccination/vaccination/faqs

What are the benefits of getting vaccinated?

- The COVID-19 vaccines **produce protection against the disease**, means there is a reduced risk of developing the illness and its consequences.
- Getting vaccinated may also **protect people around you**, because if you are protected from getting infected and from disease, you are less likely to infect someone else.

Source : [www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](http://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines)

Can we stop taking precautions after being vaccinated?

- Vaccination protects you from getting seriously ill and dying from COVID-19.

Dosage

Covaxin

The second dose of can be taken four to six weeks after the first.

Covishield

The time interval between two doses of the vaccine has been extended from four-six weeks to four-eight weeks.

Route

Intramuscular IM route

Storage

Both vaccines need to be stored and transported at +2 to +8° Celsius

- For the first fourteen days after getting a vaccination, you do not have significant levels of protection, then it increases gradually.
- I. For a single dose vaccine, immunity will generally occur two weeks after vaccination.
- II. For two-dose vaccines, both doses are needed to achieve are required to provide the highest level of best immunity possible.
- **Extent to which vaccines keeps you from being infected and passing the virus on to others is not known.**
- To help keep others safe, continue to maintain at least a 1-metre distance from others, cover a cough or sneeze in your elbow, clean your hands frequently and wear a mask, particularly in enclosed, crowded or poorly ventilated spaces.
- Always follow guidance from local authorities based on the situation and risk where you live.

Source : [www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](http://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines)

COVID-19 Vaccinations

March 2021

Can I have the second dose with a different vaccine than the first dose?

- There **isn't enough data** yet to recommend this type of combination.
- Therefore, it must be ensured that the **entire schedule of vaccination is completed by only one type of vaccine** as different COVID-19 vaccines are not interchangeable.

Source : www.mohfw.gov.in/covid_vaccination/vaccination/faqs

Should I be vaccinated if I have had COVID-19?

- Even if you have already had COVID-19, **you should be vaccinated** when it is offered to you.
- The protection that someone gains from having COVID-19 will vary from person to person, and we also don't know how long natural immunity might last.

Source : [www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](http://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines)

Do the vaccines protect against new virus variants?

- The COVID-19 vaccines are expected to **provide at least some protection against new virus variants** and are effective at preventing serious illness and death - because these vaccines create a broad immune response, and any virus changes or mutations should not make vaccines completely ineffective.
- Data continues to be collected and analysed on new variants of the COVID-19 virus.
- While we are learning more, **we need to do everything possible to stop the spread of the virus in order to prevent mutations** that may reduce the efficacy of existing vaccines.

www.who.int/news-room/feature-stories/detail/the-effects-of-virus-variants-on-covid-19-vaccines

If one is taking medicines for illness like Cancer, Diabetes, Hypertension etc, can she/he take the COVID-19 vaccine?

- **Yes.**
- Persons with one or more of these comorbid conditions are considered high risk category.
- **They need to get COVID -19 vaccination.**

Source : [www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](http://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines)

What are the contraindications for this vaccine?

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.

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-19 vaccination is to be deferred for 4-8 weeks after recovery
- Persons having active symptoms of SARS-CoV-2 infection.
- SARS-COV-2 patients who have been given anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma
- Acutely unwell and hospitalized (with or without intensive care) patients due to any illness.

Source : www.mohfw.gov.in/covid_vaccination/vaccination/faqs

A large number of children are getting affected with COVID 19 infection this year.

Few suggestions for parents

- Please don't panic.
- Children have milder symptoms and their outcome is far better compared to adults
- In case of fever only, treat only with paracetamol.
- If fever persists beyond 2-3 days, please consult a doctor on site or at least have an online consultation.
- Please do not pump up the children with unnecessary medications based upon hearsay. Most have no proven role or benefit.
- Antibiotics are not needed routinely unless there is any associated/ suspected bacterial infection.
- Please give normal diet. No restrictions on home cooked food. Sick children anyway have poor appetite.
- Routine activities like bathing with soap and water should continue.
- If checking oxygen saturation with pulse oximeter, check if the graph pattern is regular. Note the reading when the graph is regular. Take the highest reading. Less than 94% in room air repeatedly should prompt escalation of therapy/ admission.
- Only way to prevent infection is mask and hand wash. Multivitamins do not prevent infection.
- Complications if any, usually happen at the end of the 1st week, even though fever subsides by 1 or 2 days. Observe the child for 10 to 15 days
- Mothers can breast feed even if they are COVID positive, if they are not unduly sick to do so.

COVID-19 Vaccination for Pregnant and Breastfeeding Women

Although the absolute risk of severe COVID-19 in pregnancy remains low, it is now established that pregnant women are at increased risk of severe COVID-19-associated illness compared with non-pregnant women.^{1,2,3,4} Such illness can require hospitalisation, intensive care unit admission, mechanical ventilation and even cause death. Thus, preventing critical COVID-19 infection is of paramount importance for both the mother and her fetus.

Most countries have availability of COVID-19 vaccines and are offering them to priority groups. Existing COVID-19 vaccines use different technologies, including messenger RNA (mRNA), viral vectors, or recombinant proteins manufactured in a baculovirus system that are co-formulated with adjuvants.⁵ Clear guidance is needed on whether pregnant and breastfeeding women should receive a COVID-19 vaccine.

FIGO position

Given that clinical trials of COVID-19 vaccines specifically in pregnant women have not yet been conducted (some are underway or planned soon⁶), limited data are available on their efficacy and safety during pregnancy. Hence, there is not sufficient evidence to recommend the routine use of COVID-19 vaccines for pregnant or breastfeeding women. Limited data from animal studies are reassuring and do not indicate direct or indirect harmful effects on embryo/fetal development or pregnancy.⁷ Additional reassuring data come from a statement, released in the USA in the first week of February, that 20,000 pregnant women had been vaccinated with no alarming signs reported.⁸

FIGO, therefore, considers that there are no risks – actual or theoretical – that would outweigh the potential benefits of vaccination for pregnant women. We support offering COVID-19 vaccination to pregnant and breastfeeding women.

Empower women to make informed choices

FIGO urges health care providers to support pregnant women to make an informed decision regarding COVID-19 vaccination in consultation with their obstetrician. Important considerations when offering the vaccine should include the:

- level of activity of the virus in the local community
- potential efficacy of the vaccine
- lack of safety data specific to its use in pregnancy
- risk and potential severity of maternal disease, including the possible effects of the disease on the fetus (preterm birth) and newborn
- timing of vaccination during pregnancy.

Counselling should also address the expected side effects that are considered a normal part of the body's reaction to the vaccine, which is more prevalent among younger people due to overreaction of the immune system. Fever, one of the most common side effects reported with COVID-19 vaccines,⁹ can be managed by acetaminophen, which is considered safe during pregnancy and should not theoretically impact the antibody response to COVID-19 vaccines.¹⁰ Women should be particularly reassured that the existing COVID-19 vaccines are not live virus vaccines and that the mRNA vaccines do not cause any genetic changes since they do not alter human DNA.

Are you pregnant?

During the **COVID-19 pandemic**, it's more important than ever to protect yourself and your baby.

Pregnant women are at risk of severe flu. Influenza vaccination given during pregnancy protects both you and your baby for several months after birth.

Ask your healthcare provider whether a flu vaccine is right for you.



If you experience any of the following symptoms, **seek immediate medical care:**

Fever or cough that improves but then returns or worsens



Loss of speech or mobility



Difficulty breathing or shortness of breath



Pain or pressure in the chest or abdomen



Dizziness or confusion



Seizures



Severe muscle pain



Not urinating



Decreased or no movement of your baby



Because the flu vaccine doesn't protect you from **COVID-19**, follow these precautions:



Clean your hands frequently



Keep at least 1 metre distance from others



Wear a mask when 1 metre distance from others is not possible



Cough or sneeze into a bent elbow or a tissue



Avoid touching your eyes, nose and mouth



Avoid crowded public gatherings or activities



Open window

For more information visit www.who.int

Source : www.who.int/images/default-source/health-topics/coronavirus/infographics/are-you-pregnant_11_3.png?sfvrsn=71ea572b_5

Are you caring for children under the age of 5?

During the **COVID-19** pandemic, it's more important than ever to protect children from flu.

Children under 5 years old are at greater risk of severe disease or complications following infection with influenza, such as hospitalization and, more rarely, death.

Ask your healthcare provider whether a flu vaccine is right for your child.



If you suspect flu or if a child has any of these symptoms, seek immediate medical care:

High fever



Rapid breathing



Blue lips



Chest pain



Severe muscle pain



Severe vomiting



Dehydration



Not interacting when awake



Unable to drink or breastfeed



Lethargy



Seizures



Because the flu vaccine doesn't protect you from **COVID-19**, follow these precautions:



Clean your hands frequently



Keep at least 1 metre distance from others



Wear a mask when 1 metre distance from others is not possible



Cough or sneeze into a bent elbow or a tissue



Avoid touching your eyes, nose and mouth



Avoid crowded public gatherings or activities



Open window

HOW TO MONITOR & REPORT COVID-19 VACCINE SIDE EFFECTS

Health workers play a key role in ensuring the continued safety of COVID-19 vaccines

BEFORE VACCINATING

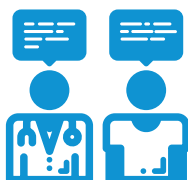


STEP ONE **ASK**

if the person getting vaccinated has ever had a severe allergic reaction to a vaccine



If **YES**, refer the person to an allergy specialist or health provider, who will recommend next steps



STEP THREE **COMMUNICATE**

common side effects after vaccination, which indicate that a person's body is building protection to COVID-19

Common side effects include:

- Arm soreness
- Mild fever
- Tiredness
- Headaches
- Muscle or joint aches



STEP TWO **ASSESS**

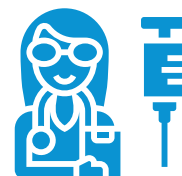
any **health or medical conditions listed as precautions** by the vaccine manufacturer or by your local immunization programme

These conditions may include:

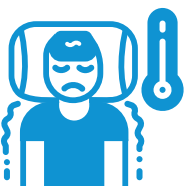
- Pregnancy
- Compromised immune system
- Severe frailty among older persons

People with these conditions are eligible for vaccination, but should be offered information & counselling

STEP FOUR **VACCINATE**



AFTER VACCINATING



STEP FIVE **OBSERVE**

the vaccinated person for 15 minutes – tell them how & **where to report severe reactions**

- Observe people with a **past vaccine allergy for 30 minutes**, after they have been approved by a specialist (step 1)

STEP SIX **INFORM**

your supervisor immediately of any **unexpected or severe reactions** during the observation period or reported later

- Complete an electronic or paper **Adverse Events Following Immunization (AEFI) form**, available online at investigation.gvsi-aei-tools.org

- Health officials will then **investigate** the event



It's extremely rare for severe health reactions to be directly caused by vaccines. But reporting & investigating adverse events will ensure that COVID-19 vaccines continue to meet high safety standards.



World Health Organization

Source : www.who.int/docs/default-source/coronaviruse/vaccine_safety_poster_final.pdf?sfvrsn=31614713_5

COVID-19

Coronavirus Symptoms

SERIOUS COVID-19 SYMPTOMS REQUIRING IMMEDIATE MEDICAL CARE

- If you develop any of these symptoms, call your healthcare provider or health facility and seek medical care immediately.
- This is not an exhaustive list. These are the most common symptoms of serious illness, but you could get very sick with other symptoms – if you have any questions, call for help immediately.



Shortness of breath/ Difficulty breathing



Loss of speech or mobility or confusion



Chest pain

MOST COMMON SYMPTOMS



Fever



Cough



Tiredness



Loss of taste or smell

LESS COMMON SYMPTOMS



Sore throat



Headache



Aches and pains



Diarrhea



A rash on the skin or discolouration of fingers or toes



Red or irritated eyes

PLEASE NOTE:

- If you live in an area where malaria, dengue or other infections are common and you have any of above symptoms, seek immediate medical care according to the local health authorities.
- Stay in touch with your primary care provider to ensure you continue to receive the routine care you need, such as medication refills, follow-ups and other routine consultations.

WHO COVID-19 CLINICAL CARE BUNDLE

This is a derivative product related to the WHO COVID-19 Living Clinical Management Guidance and WHO Living Guidelines for Therapeutics and COVID-19. To be used by health workers caring for patients with suspected or confirmed COVID-19.

To be performed, as soon as possible:



Isolate the patient. Wear medical mask, gown, gloves and eye protection. If performing an aerosol generating procedure, wear a particulate respirator.



Perform triage and clinical assessment. Check vital signs: temperature, respiratory rate, pulse, blood pressure, mental status (AVPU) and pulse oximetry.



If any signs of severe or critical COVID-19, manage airway and give oxygen therapy immediately.



Administer corticosteroids if patient has severe or critical COVID-19: 6 mg daily of dexamethasone or equivalent 150 mg of hydrocortisone (50 mg every 8 hours), 40 mg of prednisone, or 32 mg of methylprednisolone (8 mg every 6 hours or 16 mg every 12 hours).



Administer standard thromboprophylaxis dosing of anticoagulation, if no established indication for higher dose anticoagulation, and no contraindications. Enoxaparin 40 mg by subcutaneous injection every 24h or unfractionated heparin (UFH) 5000 units by subcutaneous injection every 8 or 12h. Adjust for low body weight and high BMI.



**World Health
Organization**



WHO COVID-19 CLINICAL CARE BUNDLE

*** EMERGENCY SIGN:**
Obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma and/or convulsions.

SEVERE DISEASE:

Adolescent or adult with clinical signs of pneumonia (fever, cough, dyspnoea) plus one of the following: respiratory rate > 30 breaths/min; severe respiratory distress; or $SpO_2 < 90\%$ on room air.

Child with clinical signs of pneumonia (cough or difficulty in breathing)
+ at least one of the following:

- Central cyanosis or $SpO_2 < 90\%$; severe respiratory distress (e.g. fast breathing, grunting, very severe chest indrawing); general danger sign: inability to breastfeed or drink, lethargy or unconsciousness, or convulsions.
- Fast breathing (in breaths/min): < 2 months: ≥ 60 ; 2–11 months: ≥ 50 ; 1–5 years: ≥ 40 .

CRITICAL COVID-19:

Patient presenting with acute respiratory distress syndrome, sepsis, septic shock, acute thrombosis or other conditions that normally require life-sustaining therapies.

Caution: The oxygen saturation threshold of 90% to define severe COVID-19 and should be interpreted cautiously. For example, clinicians must use their judgment to determine whether a low oxygen saturation is a sign of severity or is normal for a given patient with chronic lung disease. Similarly, a saturation > 90 – 94% on room air is abnormal (in patient with normal lungs) and can be an early sign of severe disease, if patient is on a downward trend. Generally, if there is any doubt, err on the side of considering the illness as severe.

While the diagnosis can be made on clinical grounds; chest imaging (radiograph, CT scan, ultrasound) may assist in diagnosis and identify or exclude pulmonary complications.



**World Health
Organization**

© World Health Organization 2020

<https://www.who.int/publications/i/item/clinical-management-of-covid-19>

<https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19>





Tips for Managing COVID-19 (Coronavirus) at Home for Adults

[Version 5, April 25, 2021]

Scan the QR code for detailed information!



If you have COVID-19 symptoms

CONSULT WITH A DOCTOR & GET TESTED

*Symptoms: fever, sore throat, cough, breathing difficulty, headache, body aches, loss of smell or taste



Check oxygen level (with pulse oximeter) 3-4 times/day



Wear a mask and have your family wear a mask to protect everyone



Open windows for ventilation



Stay (Isolate) at home and rest



Stay hydrated



Fever medicines (Paracetamol, Acetaminophen)

If oxygen level is 92% or more



Fever medicines (Paracetamol, Acetaminophen)



Stay hydrated



Lie on your stomach as tolerated, to improve lung oxygenation



Inhaled budesonide (steroid) - two puffs, twice daily (1600 mcg/day in total), until symptoms improve*

If oxygen level is less than 92%

CONSULT WITH A DOCTOR & SEEK HOSPITAL CARE

The following are proven treatments recommended under medical supervision



Lie on your stomach



Use oxygen



Monitor oxygen level 4-6 times/day



Dexamethasone* (steroid) 6mg orally or IV, once daily, for 5-10 days

*If Dexamethasone unavailable, one of these:

Hydrocortisone 50 mg orally or IV, three times daily, for 5-10 days
Methylprednisolone 32 mg orally or IV, once daily, for 5-10 days
Prednisolone 40 mg orally, once daily, for 5-10 days
Prednisone 40 mg orally, once daily, for 5-10 days
Steroid can be stopped at 5 days if oxygen is no longer needed

Credits: Dr. Zain Chagla, Dr. Krutika Kuppalli, Dr. Madhukar Pai, Dr. Priya Sampathkumar, Dr. Nitika Pant Pai, Dr. Celine Gounder, Dr. Kartik Cherabuddi, Dr. Lancelot Pinto, Dr. Joel Klinton, Dr. CS Pramesh
Contact: krutika1113@gmail.com

Disclaimer: This tip sheet is intended to be educational in nature and is not a substitute for clinical decision making by professionals
<https://www.indiacovidsos.org>

+ [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(21\)00160-0/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00160-0/fulltext)

* <https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.1> and <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1>

Source : www.indiacovidsos.org

Further Readings

- www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines
- www.mohfw.gov.in/covid_vaccination/vaccination/faqs.html
- www.who.int/news-room/feature-stories/detail/the-effects-of-virus-variants-on-covid-19-vaccines
- [www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines)
- www.bharatbiotech.com/images/covaxin/covaxin-publications.pdf
- www.bharatbiotech.com/images/covaxin/covaxin-fact-sheet.pdf
- www.seruminstitute.com/pdf/covishield_fact_sheet.pdf
- www.seruminstitute.com/pdf/covishield_ChAdOx1_nCoV19_corona_virus_vaccine_insert.pdf
- www.yourstory.com/socialstory/2021/04/covid-19-vaccine-may-1-18-years-old-covaxin-covishield-government-all-need-to-know
- www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines