

## Latest Research Roadmap of Approved Drugs & Vaccines for Covid-19 Recovery

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### Abstract

The coronavirus disease 2019 (COVID-19) pandemic caused and is still causing significant mortality and economic consequences all over the globe. Till date today, there are four U.S Food and Drug administration (FDA) approved vaccines, Pfizer-BioNTech, Moderna, Janssen and Novavax COVID-19 vaccines. Also, the antiviral drug remdesivir and two combinations of monoclonal antibody treatments are authorized for Emergency use (EUA) in certain patients. Furthermore, baricitinib- immune modulator was approved in Japan (April 23, 2021) for certain hospitalized adults with covid-19. Despite available vaccines and EUA, pharmacological therapy for the prevention and treatment of COVID-19 is still highly required. There are several ongoing clinical trials investigating the efficacy of clinically available drugs in treating COVID-19. In this review, latest novel pharmacological agents for the possible treatment of COVID-19 will be discussed.

COVID-19 vaccine is the most promising strategy to end the current pandemic in addition to anti-viral agents. Design of novel anti-viral agents which are specific for SARS-CoV-2 will provide more effective therapy for COVID-19 patients. Development of effective vaccines and anti-viral drugs both needs multidisciplinary cooperation. Before effective antiviral drugs for COVID-19 are available, current treatment options will come from repurposing drugs. Thus, in this review we aim to highlight potential therapeutic strategies from the viewpoints of clinicians based on updated clinical evidences, and provide a basis for future researches of effective antiviral therapies. In the future, the development of new drugs and vaccines relies on multidisciplinary cooperation among structural biologists, chemists, and medical doctors. A knowledge gap of pharmacology for COVID-19 is expected to be filled up.

**Keywords:** COVID-19; Medications; Clinical trials; Management; Prevention; Vaccines

## Introduction

The COVID-19 pandemic first appeared as a case of pneumonia of unknown cause in December 2019 in Wuhan, China. Later, it evolved to a global outbreak and was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. The WHO reported over 94 million confirmed cases of COVID-19 including 2 million deaths, globally as of 2021 [31]. It is caused by a novel virus from the family of Corona virus (CoV). This same family of virus caused the previous outbreaks of Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) in 2003-4 and 2012, respectively. The WHO defines Coronavirus as “a large family of viruses that cause illness ranging from the common cold to more severe diseases” [2].

Coronaviruses are single-stranded RNA viruses. They are highly diverse due to their sensitivity to mutation and recombination. They mainly infect humans, mammals, and birds. The SARS-CoV-2 or COVID-19 virus is thought to have originated in bats then spread to humans, possibly by contaminated meat sold in China’s meat market. Symptoms of COVID-19 may involve multiple systems including respiratory, gastrointestinal, musculoskeletal, and neurologic. Respiratory symptoms can be manifested as dry cough, chest pain, rhinorrhoea and/or nasal congestion, sore throat and shortness of breath. Gastrointestinal symptoms can present as diarrhea, nausea, vomiting, haemoptysis and abdominal pain. Finally, patients could experience nonspecific symptoms such as fever, chills, fatigue, muscle ache, loss of taste and/or smell, headaches and confusion (Wu et al., 2020) [33].

The pandemic is not over, and the health and economic losses continue to grow. It is now evident that COVID-19 will remain with us for the long life, and there are very different scenarios for how it could evolve, from a mild endemic scenario to a dangerous variant scenario. This realization wants a new strategy that manages both the uncertainty and the long-term risks of COVID-19.

In this review, we analyzed the findings of selected pharmacological agents & Vaccines against COVID-19 in terms of efficacy, safety and stage of development. All the information were taken from the updated Research, Reviews and guidelines published by CDC, FDA, WHO, NIH, etc. Our aim is to shed light on promising drugs and identify gaps in knowledge.

## Epidemiology

According to the World Health Organization (WHO), the outgrowth of viral diseases represents a serious public health risk. SARS-CoV-2, the virus liable for COVID-19 has spread to 223 countries with more than 472 million cases, and more than 6 million deaths reported globally as of March of 2022. A current epidemiological update by WHO reported that more than 200 countries around the world have notified SARS-CoV-2 variants of concern of which the newer VOC, Omicron has been reported by 76 countries so far since first being reported in November 2021. The U.S. has experienced the highest number of SARS-CoV-2 infections and COVID-19 related deaths followed by Brazil and India. In fact, COVID-19 was the third leading cause of death in the U.S. in 2020 after heart disease and cancer; with approximately 375,000 death reported (Ahmad et al., 2021) [3]. The WHO’s current estimate of the global case fatality rate for COVID-19 is 2.2%. However, the case fatality rate is affected by factors that consist of age, underlying pre-existing conditions, and severity of illness and significantly varies between countries [5].

## Pharmacological Medications in the Treatment of Covid-19

Initially, early in the pandemic, the understanding of COVID-19 and its therapeutic management was limited, creating an urgency to alleviate this new viral ailment with experimental therapies and drug repurposing [6]. Since then, due to the intense efforts of clinical researchers globally, significant advancement has been made, which has led to a better understanding of not only COVID-19 and its management but also has resulted in the development of novel therapeutics and vaccine development at an unequalled speed.

Currently, a multiple of therapeutic options are available that involve antiviral drugs (e.g., molnupiravir, paxlovid, remdesivir), anti-SARS-CoV-2 monoclonal antibodies (e.g., bamlanivimab/etesevimab, casirivimab/imdevimab), anti-inflammatory drugs (e.g., dexamethasone), immunomodulators agents (e.g., baricitinib, tocilizumab) are accessible under FDA issued Emergency Use Authorization (EUA) or being evaluated in the management of COVID-19 (Coopersmith et al., 2021) [1, 20].

The clinical applicability of these treatments is specific and is based on the severity of illness or certain risk factors. The clinical course of the COVID-19 illness occurs in 2 phases, an early phase when SARS-CoV-2 replication is greatest before or soon after the onset of symptoms. During this stage of viral replication, antiviral medications and antibody-based treatments are likely to be more effective. The later phase of the illness is driven by a hyperinflammatory state induced by the release of cytokines and the coagulation system's activation that causes a prothrombotic state. Anti-inflammatory drugs such as corticosteroids, immunomodulating therapies, or a combination of these therapies may help to battle this hyperinflammatory state more than antiviral therapies (Banerjee et al., 2021; Gandhi et al., 2020) [19, 22].

Below is an outline of the latest potential therapeutic options proposed, authorized, or approved for clinical use in the management of COVID-19.

### Key Outcomes

- Many medications are authorized for emergency use to treat COVID-19, including oral treatments like Paxlovid (nirmatrelvir and ritonavir) and Lagevrio (molnupiravir) (Davies et al. 2021) [21].
- In May 2022, the FDA authorized Olumiant (baricitinib) to deal with certain adults who are hospitalized with COVID-19. It's the second medication that's fully approved for COVID-19 [7].
- In June 2022, Pfizer stated that it's planning on submitting an application for Paxlovid's full FDA approval in people who are at high risk for spreading severe COVID-19. It's presently only recognized for emergency use [8].

### Paxlovid (nirmatrelvir and ritonavir)

Paxlovid is an oral medication that contains two antiviral drugs: nirmatrelvir and ritonavir. It comes as two different types of tablets that are packaged together. It works by blocking a protein the virus needs to make copies of itself (Mahase, 2021) [25].

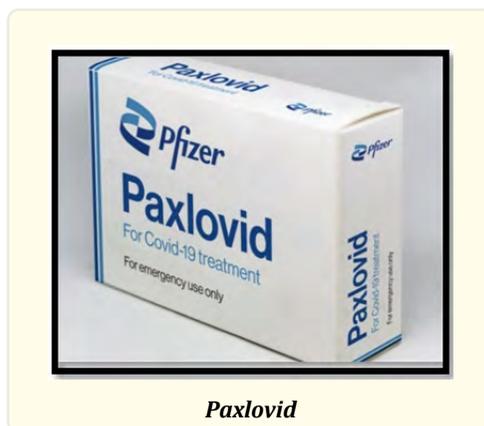
**Status:** Paxlovid was recommended for use in December 2021.

**Recommended use:** The National Institutes of Health (NIH) recommends Paxlovid as the first-choice treatment for mild-to-moderate COVID-19 in people ages 12 and older who are at high risk for severe illness (Mahase, 2021) [25].

**How it's taken:** Take three tablets by mouth 2 times a day for 5 days. Paxlovid should be taken within 5 days of getting symptoms.

**Effectiveness:** Paxlovid has been shown to lower the risk of hospitalization or death from COVID-19 by about 90% when taken within 5 days of symptom outbreak.

**Availability:** Due to high demand, it can be hard to find Paxlovid.



**Paxlovid**

### **Molnupiravir (Lagevrio)** (Singh et al., 2021) [30]

Like Paxlovid, molnupiravir (Lagevrio) is an antiviral medication. It's available as an oral capsule. It works by interfering with the process the virus uses to make copies of itself.

**Status:** Molnupiravir was sanctioned for use in December 2021.

**Recommended use:** Molnupiravir is considered to be an alternative option for treating mild-to-moderate COVID-19 in adults at high possibility of critical illness. As a result, it appears to be less effective than Paxlovid and other medications used for a similar purpose. 15

**How it's taken:** Take four capsules by oral route 2 times a day for 5 days. Molnupiravir should be taken within 5 days of catching symptoms.

**Effectiveness:** Molnupiravir has been shown to lower the risk of hospitalization or death from COVID-19 by about 30% when taken within 5 days of symptom start.

**Other considerations:** Molnupiravir should only be used by adults and shouldn't be taken in pregnancy. It can be dangerous to an unborn baby and may also affect sperm, so reliable birth control is suggested during sex.



**Molnupiravir (Lagevrio)**

### **Remdesivir (Veklury)** (Gottlieb et al., 2022) [23]

Remdesivir (Veklury) is an intravenous (IV) antiviral medication. It works by blocking an enzyme (protein) needed for the virus to replicate.

**Status:** Remdesivir was first authorized for use in May 2020 for inpatient (hospital) use. It became fully FDA-approved in October 2020 for people ages 12 and older. In January 2022, it was enlarged for outpatient use for all ages. And in April 2022, it became fully approved for certain kids who are ages 28 days and older.

**Recommended use:** The NIH presently suggests remdesivir as a second-choice option for certain non-hospitalized people at least 12 years old with mild-to-moderate COVID-19 at high risk for serious illness. This means that Paxlovid is preferred, but remdesivir is a choice if patient can't access or receive Paxlovid. It's also approved for this purpose in children who are 28 days or older and weigh at least 3 kg (about 7 pounds). Besides, remdesivir is an available option for people in the hospital who require supplemental oxygen.

**How it's given:** Remdesivir is given as an IV infusion into the vein. Non-hospitalized people receive daily infusions for 3 days. Treatment should be initiated as soon as possible after diagnosis and within 7 days of symptom start. People who've been hospitalized typically take daily infusions for 5 to 10 days.

**Effectiveness:** In certain non-hospitalized people who are at high risk for severe COVID-19, remdesivir can help lower the risk of hospitalization or death by about 87%, compared to placebo (an infusion with no medication in it). If patient is in the hospital, its effect is more varying.

**Other considerations:** In an outpatient setting, remdesivir requires travel to and from an infusion location. And it's recommended to get an infusion on 3 back-to-back days.



**Remdesivir (Veklury)**

**Remdesivir is now the first COVID-19 treatment fully approved for kids younger than 12 years old (April 25, 2022) [9]**

The FDA recently announced that remdesivir is now fully approved to treat young kids who have screened positive for COVID-19.

Specifically, it can treat kids - who are at least 28 days old and weigh 3 kg (about 7 lbs) or more - both in or out of the hospital. If it's used outside of the hospital, it should only be given to kids who have a high risk of developing severe COVID-19.

Before this approval, remdesivir was only authorized for this purpose in certain cases - it wasn't fully approved. With this approval, it's now the first and only COVID-19 treatment that's approved for kids younger than 12 years old.

**Bebtelovimab [10]**

Bebtelovimab is a monoclonal antibody medication that's injected into your vein.

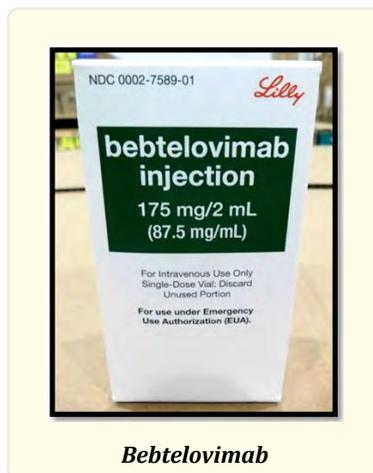
**Status:** Bebtelovimab was authorized for emergency use in February 2022.

**Recommended use:** Bebtelovimab is another medicine that can treat mild-to-moderate COVID-19 in certain people ages 12 and older who aren't in the hospital.

**How it's taken:** Bebtelovimab is injected into the vein as a single dose. It takes about 30 seconds to infuse it into the patient body.

**Effectiveness:** Official product labeling states that bebtelovimab "may be effective" at treating mild-to-moderate COVID-19. Its clinical trials were carried out before Omicron was predominant. But Eli Lilly (the manufacturer of bebtelovimab) predicts it to work against Omicron and its "stealth" subvariant.

**Availability:** The U.S. Department of Health & Human Services (HHS) has purchased 600,000 treatment courses of bebtelovimab from Eli Lilly.



### **Tocilizumab (Actemra)** (Alzghari and Acuna, 2020) [4]

Tocilizumab (Actemra) is an IV biologic medication. That means it's made from natural sources. It works by lowering an inflammation-causing chemical in the body that can be elevated in the lungs from COVID-19.

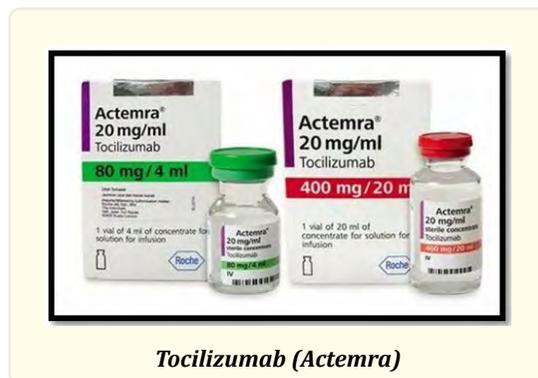
**Status:** Tocilizumab was first authorized for use in June 2021.

**Recommended use:** Tocilizumab should only be used to treat people with severe COVID-19 who are in the hospital. It shouldn't be used outside of the hospital.

**How it's given:** Tocilizumab is given as a single-dose IV infusion over 1 hour. The specific dose depends on someone's weight. One additional dose can be given if more of a response is needed.

**Effectiveness:** Before being authorized, four clinical trials showed that tocilizumab helps lower the risk of death due to COVID-19. Newer studies also suggest a similar outcome, but it seems to be most effective when used within 10 days of developing symptoms.

**Other considerations:** Other than COVID-19, tocilizumab is FDA-approved to treat autoimmune conditions like rheumatoid arthritis, giant cell arteritis, and juvenile idiopathic arthritis. This is an example of a medication that was reutilized to treat COVID-19 (Rosaset al., 2021) [27].



## Baricitinib (Olumiant) [11]

Baricitinib (Olumiant) is an oral medication. It's divided as a Janus kinase (JAK) inhibitor, and it works by reducing inflammation in the body.

**Status:** Baricitinib was first authorized for use in November 2020. It became fully FDA-approved in May 2022.

**Recommendation:** Baricitinib is only meant to treat certain people with severe COVID-19 who are in the hospital.

**How it's taken:** Take one tablet daily for 14 days or until the patient released from the hospital, whichever comes first.

**Effectiveness:** Clinical trials (ACTT-2 and COV-BARRIER) and real world studies both clarify that baricitinib can help lower the risk of death due to COVID-19 when used alongside other treatments in the hospital.

**Other conditions:** Outside of COVID-19, baricitinib is FDA-approved to treat rheumatoid arthritis. This is another example of a medication that was reutilized to treat COVID-19.



## Convalescent plasma (Simonovichet al., 2021) [29]

Convalescent plasma is the liquid part of the blood that's been collected from people who've recovered from COVID-19. It contains antibodies that can help fight COVID-19 in someone with an active infection.

**Status:** Convalescent plasma was first authorized for use in August 2020.

**Recommended use:** Latest data proves that convalescent plasma should only be used in very select situations, if recommended by healthcare provider.

**How it's given:** Convalescent plasma is infused into a vein over the course of about 1 to 2 hours. Supporting infusions may be given if required.

**Effectiveness:** There's conflicting evidence. Some studies show it may help lower the likelihood of death in certain people hospitalized with severe COVID-19. But others say it doesn't have any added value.

**Availability:** Convalescent plasma is still authorized in the U.S. to treat certain hospitalized people with COVID-19.



### Sotrovimab

Sotrovimab is a neutralizing monoclonal antibody medication. Monoclonal antibodies (mAbs) are human-made antibodies that help fight illnesses like COVID-19 [12].

**Status:** Sotrovimab was first authorized for use in May 2021, but it currently isn't authorized in any U.S. region.

**Recommended use:** REGEN-COV currently isn't recommended due to resistance concerns against the Omicron BA.2 sub-variant. Earlier, it was advocated as a second-choice option for mild-to-moderate COVID-19 in certain people ages 12 and older who aren't in the hospital.

**How it's taken:** Sotrovimab is infused into a vein as a single dose.

**Effectiveness:** In a clinical trial of non-hospitalized adults with COVID-19, sotrovimab was found to reduce the possibility of hospitalization or death by about 85%. But this was before the Omicron BA.2 sub-variant became predominant [12].



### Bamlanivimab and etesevimab

Bamlanivimab and etesevimab are two monoclonal antibody medications. They work by binding to distinct parts of the virus' spike protein, preventing it from entering and infecting your cells.

**Status:** Bamlanivimab was initially authorized for emergency use in November 2020. The FDA revised bamlanivimab’s EUA in February 2021 to be combined with etesevimab. As of January 2022, the combination is no longer authorized for use in the U.S.(Gottlieb et al., 2021) [24].

**Recommended use:** Bamlanivimab and etesevimab aren’t recommended due to resistance concerns with the Omicron variant. They were previously available to treat mild-to-moderate COVID-19 in non-hospitalized people. They were also available for post-exposure prophylaxis (PEP) in certain situations.

**How it’s given:** Both medications are infused into the vein simultaneously as a single infusion.

**Effectiveness:** New data has indicated that bamlanivimab and etesevimab are highly unlikely to be effective against the Omicron variant, which is the potent variant in the U.S.



**Bamlanivimab and etesevimab**

**REGEN-COV (casirivimab and imdevimab) [13, 14]**

REGEN-COV is an IV treatment that includes two monoclonal antibody medications: casirivimab and imdevimab. It works by targeting the virus’ spike protein, preventing it from entering and infecting your cells.

**Status:** REGEN-COV was first authorized for use in November 2020. As of January 2022, it’s no longer authorized for use in the U.S.

**Recommended use:** REGEN-COV isn’t currently recommended due to resistance concerns with the Omicron variant. It was previously available to treat mild-to-moderate COVID-19 and for PEP in people ages 12 and older who were at greater risk of serious illness.

**How it’s given:** REGEN-COV can be infused into the vein outside of the hospital, but it can also be injected under the skin.

**Effectiveness:** New data has suggested that REGEN-COV is highly unlikely to be effective against the Omicron variant, which is the predominant variant in the U.S.



**REGEN-COV (casirivimab and imdevimab)**

### ***Latest Drug Therapies under Clinical Trials: Need to Approve in Future***

As long as the COVID-19 pandemic continues, researchers and health experts will keep trying to find innovative new ways to treat and prevent COVID-19. A few medications are being studied in clinical trials, and it's possible that they could be authorized at some point in the future.

#### ***Sabizabulin***

Sabizabulin is a microtubule inhibiting-medication that's actively being studied in clinical trials. It's an oral pill that's taken once daily, and it's thought to have both antiviral and anti-inflammatory effects. It's being studied in hospitalized people with moderate-to-severe COVID-19 who are endangered for acute respiratory distress syndrome (ARDS). In addition to COVID-19, sabizabulin is also being studied for breast cancer and prostate cancer [15].

Early data suggests that sabizabulin can reduce the risk of death by about 55% in people who are hospitalized with moderate-to-severe COVID-19 (April 19, 2022).

Veru, a U.S. biopharmaceutical company, recently released interim phase 3 clinical trial data for sabizabulin. In an analysis of 150 hospitalized people with moderate-to-severe COVID-19, sabizabulin was shown to reduce the risk of death by about 55% over a 60-day (2 months) period. This was compared to placebo, a pill with no medication in it [15].

The study is still taking place, so this data could change as more findings come in. But with the current results in mind, it's been reported that Veru is planning on applying for emergency authorization in the future.

#### ***Ensovibep***

Ensovibep is an antiviral medication that's actively being studied in clinical trials. It's a one-time injection that's being evaluated as a potential way to treat COVID-19 at home.

A key study advise that ensovibep can reduce the risk of hospitalization, ER visits, or death from COVID-19 by almost 80% (January 13, 2022).

Novartis and Molecular Partners, two pharmaceutical companies, recently announced preliminary study data for an antiviral medication called ensovibep. Ensovibep is being studied as a single-dose injection that's given into the vein if person have symptomatic COVID-19 and aren't in the hospital (Rothenberger et al., 2022) [28].

In the study, ensovibep appeared to lower the risk of hospitalization, emergency room visits, or death from COVID-19 by almost 80%. This was regardless of vaccination status. Laboratory studies also suggest that it can protect against the Delta and Omicron variants. Ensovibep was also well-tolerated by people in the study. The study is still ongoing, but Novartis reportedly plans to apply for emergency authorization in the U.S. by the end of January (Rothenberger et al., 2022) [28].

**Vaccines Approved For Use:** (Walensky et al., 2021) [16, 17, 18, 26, 32]**COVID-19 vaccines approved for Manufacture for Sale or for Distribution in the various country**

No.	Vaccine	Applicant	Date of approval	Age group	Dosing schedule	Route & Storage	Shelf Life
1	<b>COVISHIELD</b> (ChAdOx1 nCoV-19 Corona Virus vaccine Recombinant)	M/s Serum Institute of India Pvt. Ltd.	27.01.2022	≥ 18 years	Two doses, 4 to 6 weeks apart	Intramuscular, 2-8°C	9 months
2	<b>COVAXIN</b> (Whole-Virion Inactivated SARSCoV-2 Vaccine)	M/s Bharat Biotech	27.01.2022	≥ 18 years	Two doses, Day 0 & 28	Intramuscular, 2-8°C	12 months

**Note:** Both COVISHIELD & COVAXIN vaccines were firstly approved for Restricted Use in Emergency Situation in the country on 03.01.2021.

**COVID-19 vaccines approved for Restricted Use in Emergency Situation in the various country**

No.	Vaccine	Applicant	Date of approval	Age group	Dosing schedule	Route & Storage	Shelf Life
1	<b>SPUTNIK-V</b> Gam COVID Vac (component I & II)	M/s Dr. Reddy's Lab. Ltd. (Importer)	12.04.2021	≥ 18 years	Two doses, Day 0 (comp I) & Day 21 (comp II)	Intramuscular, -18°C	12 months
2	<b>Moderna vaccine</b> mRNA-1273COVID-19 vaccine	M/s Cipla Ltd. (Importer)	29.06.2021	≥ 18 years	Two doses, Day 0 & 28	Intramuscular, -25°C to -15°C	7 months
3	<b>SPUTNIK-V</b> Gam COVID Vac (component I & II)	M/s Panacea Biotech Ltd	02.07.2021	≥ 18 years	Two doses, Day 0 (comp I) & Day 21 (comp II)	Intramuscular, -18°C	12 months
4	<b>Janssen Vaccine</b> COVID-19 vaccine (Ad26. COV2-S) [recombinant]	M/s Johnson & Johnson Pvt. Ltd. (Importer)	07.08.2021	≥ 18 years	Single dose	Intramuscular, -25°C to -15°C & 2-8°C	6 months
5	<b>Janssen Vaccine</b> COVID-19 vaccine (Ad26. COV2-S) [recombinant]	M/s Biological E Limited	18.08.2021	≥ 18 years	Single dose	Intramuscular, -25°C to -15°C & 2-8°C	6 months
6	<b>ZyCoV-D</b> Novel Corona Virus-2019-nCov vaccine (rDNA)	M/s Cadila Healthcare Limited	20.08.2021	≥ 12 years	Three doses Day 0, 28 & 56	Intradermal, 2-8°C	9 months
7	<b>SPUTNIK-V</b> Gam COVID Vac (component I & II)	M/s Hetero Biopharma Ltd	07.10.2021	≥ 18 years	Two doses, Day 0 (comp I) & Day 21 (comp II)	Intramuscular, -18°C	6 months

8	<b>COVAXIN</b> (Whole-Virion Inactivated SARSCoV-2 Vaccine)	M/s Bharat Biotech	24.12.2021	≥ 12 to 18 years	Two doses, Day 0 & 28	Intramuscular, 2-8°C	12 months
			26.04.2022	>6 to < 12 years			
9	<b>CORBEVAX</b> SARS-CoV-2 vaccine containing Receptor Binding Domain (RBD) of SARS-CoV-2 gene	M/s Biological E Limited	28.12.2021	≥ 18 years	Two doses, Day 0 & 28	Intramuscular, 2-8°C	12 months
			21.02.2022	≥ 12 years			
			26.04.2022	≥5 to < 12 years			
10	<b>COVOVAX</b> SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine	M/s Serum Institute of India Pvt. Ltd	28.12.2021	≥ 18 years	Two doses, Day 0 & 21	Intramuscular, 2-8°C	6 months
			08.03.2022	≥ 12 years			
11	<b>SPUTNIK Light</b> Recombinant adenoviral vector vaccine containing particles of serotype 26 containing the protein S gene of the SARS-CoV-2 virus	M/s Dr. Reddy's Lab. Ltd. (Importer)	05.02.2022	≥ 18 years	Single dose	Intramuscular, -18°C	6 months
12	<b>SPUTNIK Light</b> Recombinant adenoviral vector vaccine containing particles of serotype 26 containing the protein S gene of the SARS-CoV-2 virus	M/s Hetero Biopharma Ltd	16.03.2022	≥ 18 years	Single dose	Intramuscular, -18°C	6 months
13	<b>ZyCoV-D</b> Novel Corona Virus-2019-nCov vaccine (rDNA)	M/s Cadila Healthcare Limited	26.04.2022	≥ 12 years	Two doses, Day 0 & 28	Intradermal, 2-8°C	9 months

### Frequently Asked Questions about COVID-19 Vaccination

#### How can I prevent COVID-19?

The best way to prevent from COVID-19 is to get vaccinated with an FDA-approved or FDA-certified COVID-19 vaccine and stay up to date on your COVID-19 vaccines. Furthermore, the CDC recommends day-to-day preventive actions to help in controlling the spread of COVID-19.

### ***Which COVID-19 vaccines are FDA-approved or authorized for emergency use?***

FDA-approved COVID-19 vaccines:

Comirnaty (COVID-19 Vaccine, mRNA).

Spikevax (COVID-19 Vaccine, mRNA).

COVID-19 vaccines authorized for emergency use in the U.S.:

Janssen (J&J) COVID-19 Vaccine.

Moderna COVID-19 Vaccine.

Novavax COVID-19 Vaccine, Adjuvanted.

Pfizer-BioNTech COVID-19 Vaccine.

### ***What are the ingredients in Covid-19 Vaccines?***

Vaccine ingredients vary by manufacturer. None of the vaccines contain eggs, gelatin, latex, or preservatives. All over COVID-19 vaccines are free of metals, such as iron, nickel, cobalt, lithium, and rare earth alloys. They are also free from manufactured products such as microelectronics, electrodes, carbon nanotubes, and nanowire semiconductors. No one of the COVID-19 vaccines authorized or approved in the United States contain any live virus.

### ***Can a COVID-19 vaccine cause infertility in women?***

There is no scientific evidence to prove that FDA-authorized or FDA-approved COVID-19 vaccines could cause infertility in women. As well, infertility is not known to occur due to the natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have wrongly asserted that the COVID-19 vaccine could cause infertility in women and the FDA is concerned that this misleading information may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. The symptoms of COVID-19 differ and are unstable; a lot of people have no symptoms or only mild disease, while few have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to diverse-organ failure and death.

### ***Do Covid-19 vaccines affect your menstrual cycle (Periods)?***

Results from latest research studies visualize that people who menstruate may observe small, temporary changes in menstruation after COVID-19 vaccination, including: extend the duration of menstrual periods, reduce intervals between periods, and Excessive bleeding than usual. Regardless of these temporary changes in menstruation, there is no evidence that COVID-19 vaccines cause fertility problems.

### ***Are Covid-19 vaccines safe even though the vaccines were developed rapidly?***

Although COVID-19 vaccines were developed rapidly; research and development on vaccines like these have been underway for decades. All vaccine development steps were taken to ensure COVID-19 vaccine safety and effectiveness, including:

#### ***Clinical Trials***

All vaccines in the U.S. must go through three phases of clinical trials to ensure they are safe and effective. The phases overlapped to speed up the process, but all phases were completed.

#### ***Authorization or Approval***

Before vaccines are available to people, the U.S. Food and Drug Administration (FDA) reviews data from clinical trials. FDA has determined COVID-19 vaccines meet FDA's standards and has granted those vaccines Emergency Use Authorizations (EUAs) or full FDA approval.

### ***Tracking Safety Using Vaccine Monitoring Systems***

Like every other vaccine approved for use in the United States, COVID-19 vaccines continue to be monitored for safety and effectiveness.

### ***Why should my children & teens get vaccinated against Covid-19?***

COVID-19 can make children and teens very sick and sometimes requires treatment in a hospital. Getting eligible children and teens vaccinated against COVID-19 can help keep them from getting really sick if they do get COVID-19, including protecting them from short and long-term complications and hospitalization. Vaccinating children can also help keep them in school or daycare and safely participating in sports and other group activities.

The benefits of COVID-19 vaccination outweigh the known and potential risks. CDC recommends COVID-19 vaccines for everyone ages 6 months and older, and boosters for everyone 5 years and older, if eligible.

### ***Will Covid-19 vaccines work against new covid-19 variants?***

Data demonstrate that all of the COVID-19 vaccines currently approved or authorized in the US are highly effective in reducing risk of severe disease, hospitalization, and death. The arrival of new variants further highlights the importance of vaccination, boosters, and other prevention efforts necessary to protect against COVID-19.

Viruses continuously mutate, and public health experts predict new variants of a virus to occur. Multiple variants of SARS-CoV-2 (the virus that causes COVID-19) have been cataloged in the US and globally. The US government has developed a Variant Classification Scheme that defines three classes of SARS-CoV-2 variants:

- Variant of Interest (VOI)
- Variant of Concern (VOC)
- Variant of High Consequence (VOHC)

Scientists are noticing changes in the virus, and information about these variants is rapidly emerging. The new variants appear to spread more easily and quickly, which may lead to more cases of COVID-19; however, vaccines work well in preventing severe illness, hospitalization, and death.

### ***Are COVID-19 vaccines safe for people with liver disease, heart disease, or other chronic health conditions?***

Different studies prove that older adults and those with certain medical conditions-including cancer, chronic kidney disease, chronic lung disease, dementia, diabetes (type 1 or type 2), Down syndrome, heart disease, HIV, liver disease, and sickle cell disease-are at greater risk of severe illness or death from COVID-19 and should be vaccinated. COVID-19 vaccines are safe and effective.

## **Conclusion**

The evidence suggests that all the included vaccines are effective in preventing COVID-19. The mRNA vaccines appear most fruitful in preventing COVID-19, but viral vector vaccines sound most effectual in reducing mortality. Further trials and longer follow-up are necessary to provide better visions into the safety profile of these vaccines.

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