

COVID-19 Vaccine Information

What you need to know about COVID-19 Vaccination

Module #1: Authorized COVID-19 Vaccines



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FOR MORE INFORMATION: cdc.gov/COVID19

What you need to know about COVID-19 Vaccination

Disclaimer: This presentation is for informational purposes only. This presentation is not to provide medical advice, and should not be substituted for seeking medical advice from your health care provider. The information shared today is intended to help you make a well informed decision, and/or prepare for a more detailed conversation about COVID-19 vaccines with your health care provider.

The information shared today related to COVID-19 illness, COVID-19 vaccine information, vaccine eligibility, and vaccine appointment information is current as of March 31, 2021, but is subject to change. Please continue to frequently check the CDC website, your local and state public health department website for changes/updates in guidance about COVID-19 illness and COVID-19 vaccines.

Module #1:

Authorized COVID-19 Vaccines

COVID-19 Vaccines Emergency Use Authorization (EUA)





https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/steps-ensure-safety.html

Safety of COVID-19 vaccines is a top priority

COVID-19 vaccines are being held to the same safety standards as all vaccines.

Before Authorization



- FDA carefully reviews all safety data from clinical trials.
- ACIP reviews all safety data before recommending use.

After Authorization



FDA and CDC closely monitor vaccine safety and side effects. There are systems in place that allow CDC and FDA to watch for safety issues.





V-safe:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Who should **NOT** get vaccinated

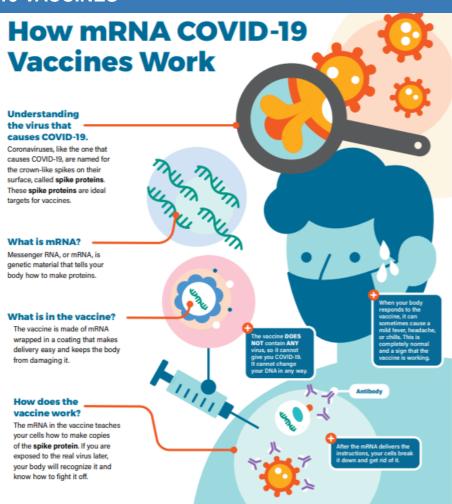
- If you have had an immediate allergic reaction—even if it was not severe—to any vaccine or injectable therapy for another disease, ask your doctor if you should get a COVID-19 vaccine. Your doctor will help you decide if it is safe for you to get vaccinated.
- If you are allergic to PEG, you should not get a mRNA COVID-19 vaccine.
 Ask your doctor if you can get the J&J/Janssen vaccine.
- If you are allergic to polysorbate, you should not get the J&J/Janssen COVID-19 vaccine. Ask your doctor if you can get an mRNA COVID-19 vaccine.
- PEG (Polyethylene glycol) and polysorbate are closely related to each other.

To learn more about allergies see: Information about COVID-19 Vaccines for People with Allergies https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html

Who should **NOT** get vaccinated

- If you have had a severe allergic reaction or an immediate allergic reaction—even if it was not severe—to any ingredient in a mRNA COVID-19 vaccine, you should not receive the mRNA vaccine. You should not get a 2nd dose of either of the currently available mRNA COVID-19 vaccines (Pfizer and Moderna).
- If you have had a severe allergic reaction or an immediate allergic reaction to any ingredient in Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine, you should not get the J&J/Janssen vaccine.
- An immediate allergic reaction means is within 4 hours of getting vaccinated, including symptoms such as hives, swelling, or wheezing (respiratory distress).

To learn more about allergies see: Information about COVID-19 Vaccines for People with Allergies https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html



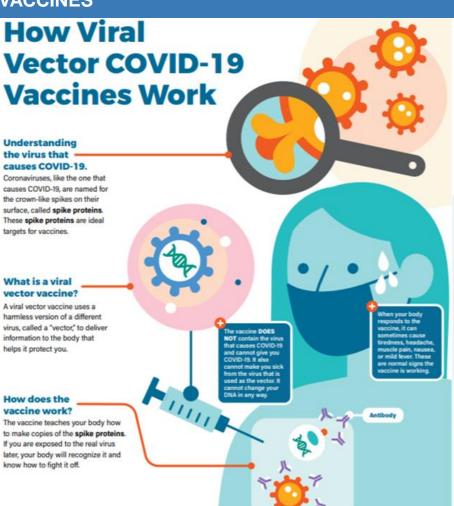
Facts about COVID-19 mRNA Vaccines

They cannot give someone COVID-19.

 mRNA vaccines do not use the live virus that causes COVID-19.

They do not affect or interact with our DNA in any way.

- mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept.
- The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.



Facts about COVID-19 Viral Vector Vaccines

They cannot give someone COVID-19 or other infections.

 Viral vectors cannot cause infection with COVID-19 or with the virus used as the vaccine vector.

They do not affect or interact with our DNA in any way.

 The genetic material delivered by the viral vector does not integrate into a person's DNA.

Authorized COVID-19 Vaccines

	Pfizer/BioNTech	Moderna	Janssen/ Johnson & Johnson	
Recommended Age	16 and older	18 and older		
Dose/frequency	2 doses given 21days, or 3weeks apart	2 doses given 28 days, or 4weeks apart	1 dose only	
Site given	Via injection in the upper arm muscle			
preventing symptomatic, laboratory-confirmed COVID-19 illness in people without evidence of previous infection.	95%	94.1%	72%* in the U.S.	
Type of vaccine	mRNA	mRNA	Viral Vector	

Authorized COVID-19 Vaccines

	Pfizer/BioNTech	Moderna	Janssen/Johnson & Johnson
Ingredients	mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hex ane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose	messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.	recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.
Does not contain	EggsPreservativesLatex	EggsPreservativesLatex	EggsPreservativesLatex

COVID-19 Vaccine Components*

Description	Pfizer-BioNTech mRNA COVID-19 Vaccine	Moderna mRNA COVID-19 Vaccine	Janssen COVID-19 Vaccine	
Active ingredients	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Viral Vector; Recombinant, replication-incompetent Ad26 vector, encoding a stabilized varian of the SARS-CoV-2 Spike (S) protein	
	2[(polyethylene glycol {PEG})- 2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80	
	1,2-distearoyl-sn-glycero-3- phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin (HBCD)	
	Cholesterol	Cholesterol	Citric acid monohydrate	
Inactive ingredients	(4-hydroxybutyl)azanediyl)bis(hexane- 6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate	
	Sodium chloride	Tromethamine	Sodium chloride	
	Monobasic potassium phosphate	Tromethamine hydrochloride	Sodium hydroxide	
	Potassium chloride	Acetic acid	Hydrochloric acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	Ethanol	
	Sucrose	Sucrose	Water for injection	

For more information: **CDC Pre-vaccination Screening Tool** https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Authorized COVID-19 Vaccines

	Pfizer/BioNTech	Moderna	Janssen/Johnson&Johnson
Common or known Side Effects	In the arm/site of injection: Effects on the rest of the body: Tiredness Headache Muscle pain Chills Joint pain Fever Nausea	 Pain Redness Swelling Effects on the rest of the body: Fatigue/Tiredness Headache Body ache Muscle pain Chills Fever Nausea 	Effects on the rest of the body: Fatigue/ Tiredness Headache Muscle pain Chills Fever Nausea
Unusual or unexpected side effects	Tenderness/swelling of lymph nodes (commonly in armpit on side of injection	Tenderness/swelling of lymph nodes (commonly in armpit on side of injection on-severe allergic reactions evere allergic reactions	

How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system**.



Respiratory:

- sensation of throat closing
- stridor (highpitched sound while breathing)
- shortness of breath
- wheeze, cough



Gastrointestinal:

- nausea
- vomiting
- diarrhea
- abdominal pain



Cardiovascular:

- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)



Skin/mucosal:

- generalized hives
- itching
- swelling of lips, face, or throat



Neurological:

- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

OTHER CONSIDERATIONS

CDC Pre-vaccination Screening Tool

https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics.

Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccines are not interchangeable. COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

For two-dose products, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses. If the vaccine product used for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered. Separate doses by at least 28 days. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

Have you ever had an allergic reaction to:

- Any component of a COVID-19 vaccine, including:
 - » Polyolyethylene (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures
- » Polysorbate, which is found in some vaccines, film-coated tablets, and intravenous steroids
- A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it unknown which component elicited the immediate allergic reaction.



Prevaccination Checklist for COVID-19 Vaccines



For vaccine recipients: Patient The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. Tyou answer "yes" to any question, it does not necessarily mean you	Name			
should not be vaccinated. It just means additional questions may be asked. f a question is not clear, please ask your healthcare provider to explain it.		Yes	No	Don't know
1. Are you feeling sick today?				
2. Have you ever received a dose of COVID-19 vaccine?				
If yes, which vaccine product did you receive? Pfizer	☐ Another product			
 Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment we would also include an allergic reaction that occurred within 4 hours that caused hives, swe 				hospital. It
A component of a COVID-19 vaccine including either of the following:				
 Polyethylene glycol (PEG), which is found in some medications, such preparations for colonoscopy procedures 	as laxatives and			
O Polysorbate, which is found in some vaccines, film coated tablets, an	d intravenous steroids.			
A previous dose of COVID-19 vaccine.				
 A vaccine or injectable therapy that contains multiple components, or vaccine component, but it is not known which component elicited the 				
4. Have you ever had an allergic reaction to another vaccine (other than CC injectable medication? (This would indude a severa allergic reaction [e.g., anaphylaxis] that required treatment we caused you to go to the hospital. It would also include an allergic reaction that occurred we swelling, or respiratory distress, including whereting.)	th epinephrine or EpiPen® or that			
 Have you ever had a severe allergic reaction (e.g., anaphylaxis) to someti of COVID-19 vaccine, or any vaccine or injectable medication? This would environmental, or oral medication allergies. 				
6. Have you received any vaccine in the last 14 days?				
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you	that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or treatment for COVID-19?	convalescent serum) as			
9. Do you have a weakened immune system caused by something such as H you take immunosuppressive drugs or therapies?	IV infection or cancer or do			
10. Do you have a bleeding disorder or are you taking a blood thinner?				
11. Are you pregnant or breastfeeding?				
12. Do you have dermal fillers?				
Form reviewed by	Date			

Other considerations

Talk to or discuss with your doctor if:

- If you are pregnant
- Have any concerns about your health condition
- If you have questions or concerns about your medications
- If you recently had COVID-19 infection
- If you received treatment for a COVID-19 infection
- If you were recently exposed to someone with COVID-19
- If you currently are not feeling well

For more information: **CDC Pre-vaccination Screening Tool** https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Other considerations

Discuss with your doctor if:

- Dermal Fillers
- Mammogram
- Other Vaccines*
- Steroid Injections
- Monthly injections, Medications, or therapies for Cancer, Autoimmune, or Rheumatologic diseases

Source: Cleveland Clinic- Should you avoid certain medications or treatments before COVID-19 vaccines. https://health.clevelandclinic.org/should-you-avoid-certain-medications-or-treatments-before-getting-vaccinated-for-covid-19/

For more information see: CDC Interim Clinical Considerations https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Emergency Use Authorization *COVID-19 Vaccine Recipient Fact sheet*

For more information about individual vaccines:

PfizerBioNtech

https://www.fda.gov/media/144414/download

Moderna

https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf

Janssen/Johnson & Johnson

https://www.cdc.gov/vaccines/covid-19/eua/janssen.html

Source: CDC https://www.cdc.gov/vaccines/covid-19/eua/index.html

FACT SHEET FOR RECIPIENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS IS YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19.

There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?

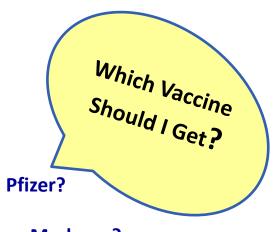
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

Revised: 12/2020

Key facts about COVID-19 Vaccines



Moderna?

Johnson & Johnson?

- All COVID-19 vaccines available in the United States are effective at preventing COVID-19.
- After complete vaccination, it typically takes about 2 weeks for the body to build protection. That means it is possible you could still get COVID-19 soon after vaccination.
- Some people who are fully vaccinated against COVID-19 will still get sick because the vaccines are not 100% effective against COVID-19 illness.
- Based on data from clinical studies, COVID-19 vaccine may also help keep you from getting seriously ill, even if you do get COVID-19.

For more information for fully vaccinated individuals :

For Vaccine Recipients





Sign up with your smartphone's browser at <u>vsafe.cdc.gov</u>

For Vaccine Provider reporting

VAERS is the nation's early warning system for vaccine safety





Vaccine Adverse Event Reporting System

co-managed by CDC and FDA

vaers.hhs.gov



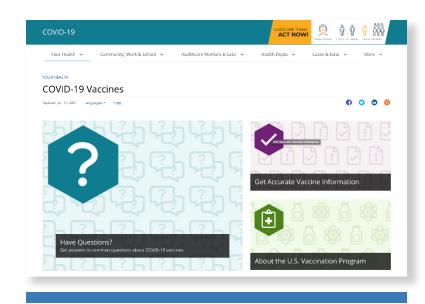
https://vaers.hhs.gov/faq.htm

https://vsafe.cdc.gov/en/

CDC COVID-19 Vaccine Websites



https://www.cdc.gov/vaccines/covid-19/index.html



https://www.cdc.gov/coronavirus/2019ncov/vaccines/index.html

Watch Next:

Vaccine Eligibility and Vaccine Appointments