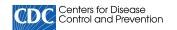
1	DAVID CHIU, State Bar #189542		
	City Attorney		
2	WAYNE SNODGRASS, State Bar #148137 TARA M. STEELEY, State Bar #231775		
3	RONALD H. LEE, State Bar #238720		
	KATE G. KIMBERLIN, State Bar #261017		
4	Deputy City Attorneys		
	City Hall, Room 234		
5	1 Dr. Carlton B. Goodlett Place		
	San Francisco, California 94102-4682		
6	Telephone: (415) 554-4655 (Steeley) (415) 554-3935 (Lee)		
7	(415) 554-3847 (Kimberlin)		
<i>'</i>	Facsimile: (415) 554-4699		
8	E-Mail: tara.steeley@sfcityatty.org		
	ronald.lee@sfcityatty.org		
9	kate.kimberlin@sfcityatty.org		
10	Attorneys for Defendants	277. A.Y.	
11	CITY AND COUNTY OF SAN FRANCISCO, E	ET AL.	
11			
12	SUPERIOR COURT OF T	HE STATE OF CALII	FORNIA
	COLDITAL		
13	COUNTY OF	SAN FRANCISCO	
14	UNLIMITED	JURISDICTION	
17	OT (EII) ITEE	Verdsbierion	
15			
	UNITED SF FREEDOM ALLIANCE,	Case No. CGC-22-59	97428
16	BHANU VIKRAM, CARSON R.	EVILIDITE A D.T.	O DEOLIEST FOR
17	SCHILLING, CHRISTA L. FESTA,	EXHIBITS A – B T	E IN SUPPORT OF
1 /	CHRISTIANNE T. CROTTY, DENNIS M.		TY AND COUNTY OF SAN
18	CALLAHAN, JR., FAIMING CHEUNG,		AL.'S DEMURRER TO
	and JESSICA KWOK-BO LINDSEY,	THE SECOND AM	ENDED COMPLAINT
19	D1-1-4100-		OF CIVIL RIGHTS AND
•	Plaintiffs,	DECLARATORY A	AND INJUNCTIVE RELIEF
20	Vs.	Haaring Datas	June 21, 2022
21		Hearing Date: Hearing Judge:	Judge Richard B. Ulmer
41	CITY AND COUNTY OF SAN	Time:	9:30 a.m.
22	FRANCISCO, a municipal corporation and	Place:	Dept. 302
	administrative division of the State of		•
23	California, et al., and Does 1 through 100,	Date Action Filed:	January 4, 2022
ا ر	inclusive,	Trial Date:	None set
24	Defendants.		
25			
26		_	
27			
, , I	·		

28

EXHIBIT A

TO

REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS CITY AND COUNTY OF SAN FRANCISCO, ET AL.'S DEMURRER TO SECOND AMENDED COMPLAINT FOR VIOLATION OF CIVIL RIGHTS AND DECLARATORY AND INJUNCTIVE RELIEF



Español (Spanish)

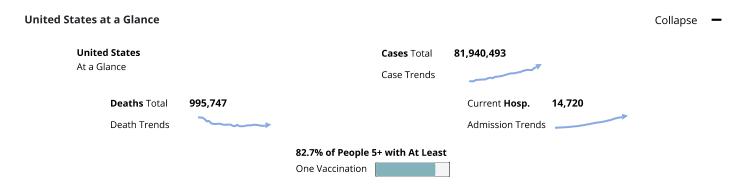
COVID Data Tracker

Maps, charts, and data provided by CDC, updates daily by 8 pm ET

COVID-19 Home >



CDC recommends use of COVID-19 Community Levels to determine the impact of COVID-19 on communities and take action. Community Transmission levels are provided for healthcare facility use only.



Data Tracker Home

Cases, Deaths, & Testing

Case & Death Demographic Trends

Vaccination Distribution & Coverage

Vaccine Effectiveness & Breakthrough Surveillance

Health Equity

Pediatric

Pregnancy

People at Increased Risk

Wastewater Surveillance

United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction

Maps, charts, and data provided by CDC, updated Mon-Sat by 8 pm ET^\dagger

View Footnotes and Download Data

TOTAL CASES

81,940,493

+98.354 New Cases

7 DAY CASE RATE PER 100,000

165

TOTAL DEATHS

995,747

+356 New Deaths

CDC | Data as of: Wednesday, May 11, 2022 1:15 PM ET. Posted: Wednesday, May 11, 2022 2:41 PM ET

View:

Cases

O Deaths

Time period:Last 7 Days

O Count

O Since Jan 21, 2020

Rate per 100,000

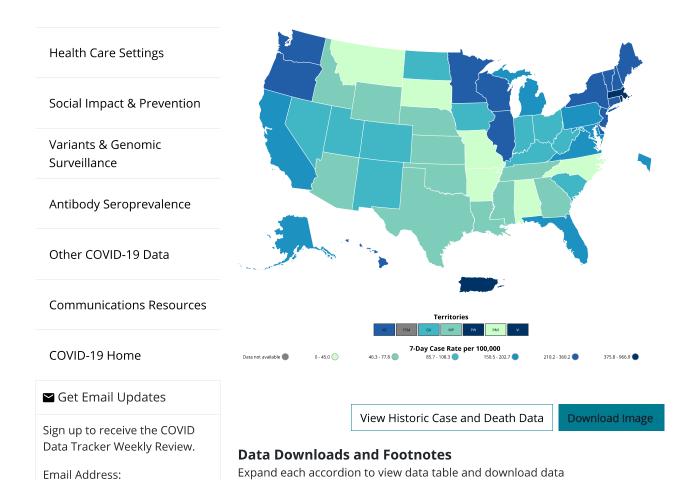
Metric:

Tests Performed

O Percent Positive

This shows the number of COVID-19 cases for every 100,000 people over the last 7 days, allowing you to compare areas with different population sizes.

US COVID-19 7-Day Case Rate per 100,000, by State/Territory





Data Table for Cumulative Cases per 100k in Last 7 Days
Footnotes

+

Wondering what all the data mean?

CDC's new <u>COVID Data Tracker Weekly Review</u> helps you stay up-to-date on the pandemic with weekly visualizations, analysis, and interpretations of key data and trends.

How does COVID-19 Spread?

Learn more

Information on US COVID-19 Cases Caused by Variants

Learn more <u>here</u>

Do you need information on testing?

Find it here

<u>View and Download COVID-19 Case Surveillance Public Use Data with</u>

<u>Geography</u>

Cite COVID Data Tracker

Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services, CDC; 2022, May 12. https://covid.cdc.gov/coviddata-tracker

COVID-19 Home >

All COVID-19 topics including prevention, travel, work, and school

HAVE QUESTIONS?

 \Box

Visit CDC-INFO

C

Call 800-232-4636

 \sim

Email CDC-INFO

(<u>L</u>)

Open 24/7

CDC INFORMATION

About CDC

Jobs

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File Viewers & Players

Privacy

FOIA

No Fear Act

OIG

Nondiscrimination

Accessibility

Vulnerability Disclosure Policy

CONNECT WITH CDC



U.S. Department of Health & Human Services

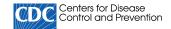
USA.gov

CDC Website Exit Disclaimer ${\color{red} \square}$

EXHIBIT B

TO

REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS CITY AND COUNTY OF SAN FRANCISCO, ET AL.'S DEMURRER TO SECOND AMENDED COMPLAINT FOR VIOLATION OF CIVIL RIGHTS AND DECLARATORY AND INJUNCTIVE RELIEF





COVID-19

Pfizer-BioNTech COVID-19 Vaccine (also known as COMIRNATY): Overview and Safety

Updated Apr. 27, 2022

Recommended for People 5 Years and Older	
Stay up to date	
Guidance for people who are immunocompromised	

General Information

Manufacturer: Pfizer, Inc., and BioNTech

Number of Shots: 2 doses in the primary series, given 3-8 weeks apart.

People ages 5 years and older who are moderately or severely immunocompromised should get a third dose at least 4 weeks after their second dose.

Booster Shot: People ages 12 years and older who received a Pfizer-BioNTech primary series should get a booster. Some people can also choose to receive a second booster.

Type of Vaccine: mRNA

How Given: Shot in the muscle of the upper arm

Does NOT Contain: Eggs, preservatives, latex, metals

See full list of ingredients

Name: BNT162b2

Brand name: COMIRNATY

Pfizer-BioNTech (COMIRNATY) Name Change

Pfizer-BioNTech (COMIRNATY) received U.S. Food and Drug Administration (FDA) approval on August 23, 2021, for individuals ages 16 years and older. Once vaccines are approved by the FDA, companies can market the vaccines under brand names. COMIRNATY is the brand name for the Pfizer-BioNTech COVID-19 vaccine. After FDA approval, the FDA-authorized Pfizer-BioNTech COVID-19 vaccine for individuals ages 16 years and older was marketed as COMIRNATY. **No change was made to the vaccine's formula** with the name change.

The Pfizer-BioNTech vaccine label remains for individuals ages 5–15 years since the vaccine is authorized but not yet approved for this age group.

Safety Data Summary

- COVID-19 vaccines have undergone—and will continue to undergo—the most intensive safety monitoring in U.S. history.
 Evidence from the hundreds of millions of COVID-19 vaccines already administered in the United States, and the billions of vaccines administered globally, demonstrates that they are safe and effective.
- Side effects that happen within 7 days of getting vaccinated are common but are mostly mild. Some people have side
 effects that affect their ability to do daily activities.
- Side effects throughout the body (such as fever, chills, tiredness, and headache) are more common after the second dose of the vaccine.
- Severe allergic reactions to vaccines are rare but can happen.
- There is a rare risk of myocarditis and pericarditis associated with mRNA COVID-19 vaccination, mostly among males
 ages 12 through 39 years. The rare risk may be further reduced with a longer interval between the first and second dose.
 Learn more about the timing for your second dose.

Learn more about vaccine safety monitoring after a vaccine is authorized or approved for use.

How Well the Vaccine Works

- Vaccines reduce the risk of COVID-19, including the risk of severe illness and death among people who are fully vaccinated.
- COVID-19 vaccines are effective, but studies have shown vaccine protection declines over time—especially with the Omicron variant. Learn more about getting a booster shot to enhance or restore protection against COVID-19.
- All FDA-approved or authorized COVID-19 vaccines provide substantial protection against COVID-19 hospitalization and death.
- · CDC will continue to provide updates as we learn more.

Learn about demographic information for people ages 16 years and older ☑ who participated in the trials.

Pfizer-BioNTech COVID-19 Vaccine Ingredients

All COVID-19 vaccine ingredients are safe. Nearly all of the ingredients in COVID-19 vaccines are ingredients found in many foods – fats, sugars, and salts. The Pfizer-BioNTech COVID-19 vaccine also contains a harmless piece of messenger RNA (mRNA). The COVID-19 mRNA teaches cells in the body how to create an immune response to the virus that causes COVID-19. This response helps protect you from getting sick with COVID-19 in the future. After the body produces an immune response, it discards all of the vaccine ingredients, just as it would discard any substance that cells no longer need. This process is a part of normal body functioning.

All COVID-19 vaccines are manufactured with as few ingredients as possible and with very small amounts of each ingredient. Each ingredient in the vaccine serves a specific purpose as seen in the table below.

Pfizer-BioNTech has updated the formulation of the Pfizer-BioNTech COVID-19 vaccine. The updated formulation has the same active ingredients as the previous formulation but uses different stabilizers (ingredients that help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored). These changes allow for easier shipping and longer storage of vaccines at refrigerator temperatures. This will help improve access to vaccines for people who need them and will decrease waste.

The previous formulation for people ages 12 years and older is no longer being distributed, and once the doses of that formulation have been used, only the updated formulation will be available. Both formulations can be used interchangeably

without any safety or effectiveness concerns. Check with your healthcare provider about which formulation they carry if you are concerned about any of the ingredients.

Ingredients in the original Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older

The original Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older contains the following ingredients:

Type of Ingredient Type of Ingredient		
Ingredient Ingredient		
Purpose Purpose		

Type of Ingredient

Messenger ribonucleic acid (mRNA)

Ingredient

• Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Purpose

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.

Type of Ingredient

Lipids (fats)

Ingredient

- 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- · Cholesterol (plant derived)
- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)

Purpose

Work together to help the mRNA enter cells.

Type of Ingredient

Salts and sugar

Ingredient

- · Dibasic sodium phosphate dihydrate
- · Monobasic potassium phosphate
- Potassium chloride (common food salt)
- Sodium chloride (basic table salt)
- Sucrose (basic table sugar)

Purpose

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Messenger ribonucleic acid (mRNA):

Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Purpose

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.

Lipids (fats):

- 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- Cholesterol (plant derived)
- (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)

Purpose

Work together to help the mRNA enter cells.

Salts and sugar:

- · Dibasic sodium phosphate dihydrate
- Monobasic potassium phosphate
- · Potassium chloride (common food salt)
- · Sodium chloride (basic table salt)
- Sucrose (basic table sugar)

Purpose

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Ingredients in children's Pfizer-BioNTech COVID-19 vaccine and the updated formulation for people ages 12 years and older

The Pfizer-BioNTech COVID-19 vaccine for people ages 5 through 11 years old and the updated formulation of the Pfizer-

BioNTech COVID-19 vaccine for people ages 12 years and older contain the following ingredients. While the ingredients are the same for all ages, people ages 12 years and older receive a higher dosage than children ages 5 through 11 years old.

Type of Ingredient
Type of Ingredient

Ingredient Ingredient

Purpose Purpose

Type of Ingredient

Messenger ribonucleic acid (mRNA)

Ingredient

• Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Purpose

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.

Type of Ingredient

Lipids (fats)

Ingredient

- 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- · Cholesterol (plant derived)
- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)

Purpose

Work together to help the mRNA enter cells.

Type of Ingredient

Sugar and acid stabilizers

Ingredient

- Sucrose (table sugar)
 - Tromethamine

Tromethamine hydrochloride

Purpose

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Messenger ribonucleic acid (mRNA):

Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Purpose

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.

Lipids (fats):

- 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- Cholesterol (plant derived)
- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)

Purpose

Work together to help the mRNA enter cells.

Sugar and acid stabilizers:

- Sucrose (table sugar)
- Tromethamine
- · Tromethamine hydrochloride

Purpose

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Ingredients that are NOT used in COVID-19 vaccines

The above table lists ALL ingredients in the Pfizer-BioNTech COVID-19 vaccine. There are NO ingredients in this vaccine beyond what is listed in the table. The Pfizer-BioNTech COVID-19 vaccine has:

- No preservatives like thimerosal or mercury or any other preservatives.
- No antibiotics like sulfonamide or any other antibiotics.
- No medicines or therapeutics like ivermectin or any other medications.
- No tissues like aborted fetal cells, gelatin, or any materials from any animal.
- **No food proteins** like eggs or egg products, gluten, peanuts, tree nuts, nut products, or any nut byproducts (COVID-19 vaccines are not manufactured in facilities that produce food products).
- **No metals** like iron, nickel, cobalt, titanium, rare earth alloys, or any manufactured products like microelectronics, electrodes, carbon nanotubes or other nanostructures, or nanowire semiconductors.
- No latex. The vial stoppers used to hold the vaccine also do not contain latex.

Related Pages

-) Possible Side Effects
- > Safety of COVID-19 Vaccines
- > Benefits of Getting Vaccinated
- > How Vaccines Work
-) mRNA Vaccines



For Healthcare Workers

Pfizer-BioNTech COVID-19 Vaccine: General information, schedule, and administration overview.

Resources

Pfizer-BioNTech COVID-19 Vaccine for People 12 Years of Age and Older Fact Sheet for Recipients and Caregivers [PDF − 6 pages]

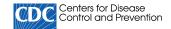
☐

Pfizer-BioNTech COVID-19 Vaccine for People 5 through 11 Years of Age Fact Sheet for Recipients and Caregivers [PDF − 6 pages]

☐

Last Updated Apr. 27, 2022

7 of 7





COVID-19

Moderna COVID-19 Vaccine (also known as Spikevax): Overview and Safety

Updated May 5, 2022

Recommended for People 18 Years and Older

Stay up to date

Guidance for people who are immunocompromised

General Information

Manufacturer: ModernaTX, Inc.

Number of Shots: 2 doses in the primary series, given 4–8 weeks apart.

People ages 18 years and older who are moderately or severely immunocompromised should get a third dose at least 4 weeks after their second dose.

Booster Shot: People ages 18 years and older who received a Moderna primary series should get a booster. Some people can also choose to receive a second booster.

Type of Vaccine: mRNA

How Given: Shot in the muscle of the upper arm

Does NOT Contain: Eggs, preservatives, latex, metals

See full list of ingredients below

Name: mRNA-1273

Brand name: Spikevax

Moderna (Spikevax) Name Change

Moderna (Spikevax) COVID-19 vaccine received U.S. Food and Drug Administration (FDA) approval on January 31,2022, for individuals ages 18 years and older. Once vaccines are approved by the FDA, companies can market the vaccines under brand names. Spikevax is the brand name for the Moderna COVID-19 vaccine. The FDA-authorized Moderna COVID-19 vaccine for individuals ages 18 years and older will now be marketed as Spikevax. **No change has been made to the vaccine's formula** with the name change.

Safety Data Summary

1 of 5 5/12/2022, 12:11 PM

COVID-19 vaccines have undergone—and will continue to undergo—the most intensive safety monitoring in U.S. history. Evidence from the hundreds of millions of COVID-19 vaccines already administered in the United States, and the billions of vaccines administered globally, demonstrates that they are safe and effective.

Side effects that happen within 7 days of getting vaccinated are common but are mostly mild. Some people have reactions that affect their ability to do daily activities.

Side effects throughout the body (such as fever, chills, tiredness, and headache) are more common after the second dose of the vaccine.

Severe allergic reactions to vaccines are rare but can happen.

There is a rare risk of myocarditis and pericarditis associated with mRNA COVID-19 vaccination, mostly among males ages 12 through 39 years. The rare risk may be further reduced with a longer interval between the first and second dose. Learn more about the timing for your second dose.

Learn more about vaccine safety monitoring after a vaccine is authorized or approved for use.

How Well the Vaccine Works

- Vaccines reduce the risk of COVID-19, including the risk of severe illness and death among people who are fully vaccinated.
- COVID-19 vaccines are effective, but studies have shown vaccine protection declines over time especially with the Omicron variant. Learn more about getting a booster shot to enhance or restore protection against COVID-19.
- All FDA-approved or authorized COVID-19 vaccines provide substantial protection against COVID-19 hospitalization and death
- CDC will continue to provide updates as we learn more.

Learn about demographic information for people who participated in the trials [PDF - 54 pages] [...

Moderna COVID-19 Vaccine Ingredients

All COVID-19 vaccine ingredients are safe. Nearly all the ingredients in COVID-19 vaccines are ingredients found in many foods—fats, sugars, and salts. The Moderna COVID-19 vaccine also contains a harmless piece of messenger RNA (mRNA). The COVID-19 mRNA teaches cells in the body how to create an effective immune response to the virus that causes COVID-19. This response helps protect you from getting sick with COVID-19 in the future. After the body produces an immune response, it discards all the vaccine ingredients, just as it would discard any substance that cells no longer need. This process is a part of normal body functioning.

All COVID-19 vaccines are manufactured with as few ingredients as possible and with very small amounts of each ingredient. Each ingredient in the vaccine serves a specific purpose as seen in the table below.

In the past, there has been one formula for the Moderna COVID-19 vaccine. A full dose of this formula (0.5 mL) is used for the primary series, and a half dose (0.25 mL) is given as a booster. Now, Moderna makes a second formula for booster doses only. This formula is 0.5 mL like the primary dose vaccine. It also includes all of the same ingredients, but some of the ingredients are in different amounts.

Full list of ingredients

The Moderna COVID-19 vaccine contains the following ingredients:

Type of Ingredient
Type of Ingredient

Ingredient Ingredient

Purpose

Purpose

Type of Ingredient

Messenger ribonucleic acid (mRNA)

Ingredient

• Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Purpose

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.

Type of Ingredient

Lipids (fats)

Ingredient

- PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- BotaniChol® (non-animal origin cholesterol)
- SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate

Purpose

Work together to help the mRNA enter cells.

Type of Ingredient

Salt, sugar, acid stabilizers, and acid

Ingredient

- Sodium acetate
- Sucrose (basic table sugar)
- Tromethamine
- · Tromethamine hydrochloride
- · Acetic acid (the main ingredient in white household vinegar)

Purpose

3 of 5

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Messenger ribonucleic acid (mRNA):

Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Purpose

Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps to protect the body from getting sick with COVID-19 in the future.

Lipids (fats):

- PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- BotaniChol® (non-animal origin cholesterol)
- SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate

Purpose

Work together to help the mRNA enter cells

Salt, sugar, acid stabilizers, and acid:

- Sodium acetate
- Sucrose (basic table sugar)
- Tromethamine
- Tromethamine hydrochloride
- Acetic acid (the main ingredient in white household vinegar)

Purpose

Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Ingredients that are NOT used in COVID-19 vaccines

The above table lists ALL ingredients in the Moderna COVID-19 vaccine. There are NO ingredients in this vaccine beyond what is listed in the table. The Moderna COVID-19 vaccine has

- No preservatives like thimerosal or mercury or any other preservatives.
- No antibiotics like sulfonamide or any other antibiotics.
- No medicines or therapeutics like ivermectin or any other medications.
- No tissues like aborted fetal cells, gelatin, or any materials from any animal.
- No food proteins like eggs or egg products, gluten, peanuts, tree nuts, nut products, or any nut byproducts (COVID-19 vaccines are not manufactured in facilities that produce food products).
- No metals like iron, nickel, cobalt, titanium, rare earth alloys, or any manufactured products like microelectronics, electrodes, carbon nanotubes or other nanostructures, or nanowire semiconductors.
- No latex. The vial stoppers used to hold the vaccine also do not contain latex.

Related Pages

4 of 5 5/12/2022, 12:11 PM

- > Possible Side Effects
- > Safety of COVID-19 Vaccines
- > Benefits of Getting Vaccinated
-) How Vaccines Work
-) mRNA Vaccines



For Healthcare Workers

Moderna COVID-19 Vaccine: General information, schedule and administration overview.

More Information

Moderna's COVID-19 Vaccine Fact Sheet for Recipients and Caregivers [PDF − 6 pages]

☐

MMWR: Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021

Safety and Reactogenicity Data

Last Updated May 5, 2022

Janssen COVID-19 Vaccine

May 5, 2022: The FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals. Read the <u>press release (/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals).</u>

	Fact Sheets and FAQs
	Fact Sheet Translations
Información sobre las	vacunas para el COVID-19 (https://www.fda.gov/about-fda/fda-en-espanol/informacion-sobre-las-vacunas-para-el-

Janssen COVID-19 Vaccine is available under EUA to prevent COVID-19 in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine. For these individuals, the Janssen COVID-19 vaccine is authorized as:

- · a single primary vaccination dose
- a single booster dose at least two months after completing primary vaccination with the vaccine
- a heterologous (or "mix and match") single booster dose following completion of primary vaccination with a
 different available COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as
 that authorized for a booster dose of the vaccine used for primary vaccination. View COVID-19 vaccine
 booster eligibility (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/doi-qualify-covid-19-vaccine-booster-and-which-one).

On February 27, 2021, FDA issued an EUA for the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older.

On May 5, 2022, the U.S. Food and Drug Administration limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

Emergency Use Authorization Status:

Authorized

Name:

Janssen COVID-19 Vaccine

Manufacturer:

Janssen Biotech Inc., a Janssen Pharmaceutical Company of Johnson & Johnson

Authorized Use

1 of 5 5/13/2022, 5:35 AM

For the prevention of Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

Common Side Effects

Janssen COVID-19 Vaccine | FDA

The most commonly reported side effects were pain at the injection site, headache, fatigue, muscle aches and nausea. Most of these side effects occurred within 1-2 days following vaccination and were mild to moderate in severity and lasted 1-2 days. <u>Learn more (/media/146305/download)</u>.

Fact Sheets (English) and FAQs

Information	Last Updated
Fact Sheet for Healthcare Providers Administering Vaccine (/media/146304/download)	May 5, 2022
Fact Sheet for Recipients and Caregivers (/media/146305/download)	May 5, 2022
Frequently Asked Questions on the Janssen COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine-frequently-asked-questions)	February 16, 2022

Regulatory Information

Information	Date
Decision Memorandum (/media/158318/download)	May 5, 2022
<u>Letter of Authorization (https://www.fda.gov/media/146303/download)</u> (Reissued)	May 5, 2022
Concurrence Letter (/media/157554/download)	April 7, 2022
Concurrence Letter (/media/156787/download)	March 4, 2022
Letter Granting EUA Amendment (/media/155862/download)	January 31, 2022
Letter Granting EUA Amendment (https://www.fda.gov/media/155391/download)	January 11, 2022
Addendum to Jan 7, 2022 Review Memorandum (/media/155467/download)	January 7, 2022
Review Memorandum (/media/155466/download)	January 7, 2022
Decision Memorandum Addendum (/media/155547/download)	January 6, 2021
Decision Memorandum Addendum (/media/155236/download)	December 30, 2021
Addendum to Dec. 22, 2021 Review Memorandum (/media/155671/download)	December 22, 2021
Review Memorandum (/media/155670/download)	December 22, 2021
Letter Granting EUA Amendment (/media/154870/download)	December 14, 2021
<u>Letter of Authorization (/media/146303/download)</u> (Reissued)	November 19, 2021
Decision Memorandum Addendum (/media/154359/download)	November 18, 2021

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Information	Date
FDA Decision Memorandum Addendum (/media/153944/download)	November 5, 2021
Concurrence Letter (/media/153931/download)	November 5, 2021
Memorandum to the File (/media/153439/download)	October 20, 2021
Decision Memorandum (/media/153441/download)	October 20, 2021
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar /vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement)	October 15, 2021
FDA Decision Memorandum Addendum (/media/152567/download)	September 29, 2021
Concurrence Letter (/media/152547/download)	September 29, 2021
FDA Decision Memorandum Addendum (/media/152170/download)	September 14, 2021
Concurrence Letter (/media/152171/download)	September 14, 2021
FDA Decision Memorandum Addendum (/media/152100/download)	September 8, 2021
Concurrence Letter (https://www.fda.gov/media/152046/download)	September 8, 2021
Letter Granting EUA Amendment (/media/151868/download)	August 30, 2021
Concurrence Letter (/media/151141/download) (shelf life extension to 6 months)	July 28, 2021
FDA Decision Memorandum Addendum (/media/150745/download)	July 13, 2021
Concurrence Letter (/media/150743/download)	July 13, 2021
Letter Granting EUA Amendment (/media/150723/download)	July 12, 2021
Concurrence Letter (/media/150136/download) (Reissued)	July 2, 2021
Concurrence Letter (/media/150163/download) (Reissued)	July 2, 2021
Concurrence Letter (/media/150567/download)	July 2, 2021
FDA Decision Memorandum Addendum (/media/150571/download)	July 1, 2021
FDA Decision Memorandum Addendum (/media/150139/download)	June 15, 2021
FDA Decision Memorandum (/media/150081/download)	June 11, 2021
Concurrence Letter (/media/150064/download) (concurring with the extension of the shelf-life of Janssen COVID-19 Vaccine stored at 2-8°C, from 3 months to 4.5 months)	June 10, 2021
Letter Granting EUA Amendment (/media/147865/download)	April 23, 2021
Letter Granting EUA Amendment (/media/147194/download)	March 29, 2021
FDA Decision Memorandum (/media/146338/download)	February 27, 2021
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar /vaccines-and-related-biological-products-advisory-committee-february-26-2021-meeting-announcement)	February 26, 2021

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Information Date

Media Materials and Webcasts

Information	Date
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals)	May 5, 2022
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines)	October 20, 2021
Media Call (https://youtu.be/rou7tf4vaUU) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 20, 2021
Advisory Committee Meeting Webcast (https://youtu.be/c-H40GrvWz4) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 15, 2021
<u>Press Release (/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough)</u>	April 23, 2021
Joint FDA and CDC Press Conference (https://youtu.be/Nf_OuB1rBi0) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	April 23, 2021
<u>Joint CDC and FDA Statement (/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine)</u>	April 13, 2021
Joint FDA and CDC Media Call (https://youtu.be/_ELXnGYgsJY) [(http://www.fda.gov/about-fda/website-policies/website-disclaimer)	April 13, 2021
Media Call (https://youtu.be/m_eSKpm19zk) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	February 27, 2021
Press Release (/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine)	February 27, 2021
Advisory Committee Meeting Webcast (https://youtu.be/Qd7mlCD-rEA) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	February 26, 2021

Translations of the Fact Sheet for Recipients and Caregivers

接受者和护理者须知 (/media/146685/download) (May 5, 2022)	中文 (Chinese, Simplified)
<u>환자와 의료진을 위한 정보지 (/media/146839/download)</u> (May 5, 2022)	한국어 (Korean)
HOJA INFORMATIVA PARA RECEPTORES Y PROVEEDORES DE CUIDADO (/media/146762/download) (May 5, 2022)	Español (Spanish)

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