VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE

FOR 5 THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.[1]

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. 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 leading to death. 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.

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

[1] You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to your child as an injection into the muscle.
The vaccine is administered as a 2-dose series, 3 weeks apart.
The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

Your child should not get the vaccine if your child:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE VACCINE?

The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

WHAT ARE THE BENEFITS OF THE VACCINE?
The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?
For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?
No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

KEEP YOUR CHILD'S VACCINATION CARD
When your child gets the first dose, you will get a vaccination card to show when to return for your child's next dose(s) of the vaccine. Remember to bring the card when your child returns.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY CHILD'S VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based

on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1486-0.3

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 09/30/2021

COVID-19 Vaccination Administration Form

Section 1: To be completed by Client or Parent/Legal Guardian (if client less than 16 years of age)

Name:	**Date of Birth:**	**Age:**	**Race:**	**Sex:**
Street Address:	**Telephone:** ☐Cell ☐ Home			
City/State:	**County:**		**Zip:**	
Preferred Method of Contact: ☐Call ☐Mail	**Preferred Phone/Address (if different from above):**			
Emergency Contact:	**Emergency Phone:**			

THE FOLLOWING QUESTIONS APPLY TO THE PERSON BEING VACCINATED:	**YES**	**NO**
1.Are you feeling sick today or have you tested + for COVID in the last 2 weeks?		
2.Have you received a previous dose of COVID-19 vaccine? If yes, list the dates and manufacturers: Dose #1: _____ Dose #2: _____ Dose #3: _____		
3. Have you ever had an allergic reaction to a previous dose of COVID-19 vaccine or to any component of the COVID-19 vaccine, such as polyethylene glycol (PEG) or polysorbate?		
4.Have you ever had an allergic reaction for which you received epinephrine (EpiPen) or were seen in the hospital? Please Explain_____		
5.Have you received COVID monoclonal antibodies or convalescent plasma in the last 90 days?		
6.Do you have a bleeding disorder or are you taking a blood thinner?		
7. Do you have a history of one of the following conditions? • Multisystem Inflammatory Syndrome (MIS-Child or MIS-Adult) • Myocarditis/pericarditis (including following previous mRNA COVID-19 vaccine)		
8. Do you have a history of dermal fillers? (Provide standing order discharge instructions for dermal fillers)		
9. Do you have a history of Guillain-Barre Syndrome? (see **Janssen Precautions**, if applicable)		
10. Do you have a history of thrombosis with thrombocytopenia? (see **Janssen Precautions**, if applicable)		
11.Do you have any of the following medical condition(s)? **(Pfizer and Moderna- dose #3 ≥ 28 days)** • Active treatment for solid tumor and hematologic malignancies • Receipt of solid-organ transplant and taking immunosuppressive therapy • Receipt of CAR-T-cell or hematopoietic stem cell transplant (2 years of transplantation or taking immunosuppression therapy) • Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes) • Advanced/untreated HIV infection, active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemo agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, other biologic agents that are immunosuppressive or immunomodulatory		
12. Do you have one of the following conditions and have completed the Pfizer or Moderna 2-dose primary vaccination series? **(Pfizer and Moderna ONLY- dose #3 booster ≥ 6 months)** • 65 years of age and older • Resident of a long-term care facility • 18 years of age and older with cancer, chronic kidney disease, chronic lung disease, dementia or other neurologic conditions, diabetes, down syndrome, heart conditions (including, but not limited to, heart failure, coronary artery disease, cardiomyopathies, and hypertension), HIV, liver disease, overweight/obesity, pregnancy, sickle cell disease or thalassemia, current or former smoker, solid organ or stem cell transplant, stroke or cerebrovascular disease, or substance abuse • Individuals 18 years of age or older who are at increased risk for COVID-19 exposure and transmission because of occupational orinstitutional setting		

I have completed SECTION 1. By my signature below as client, parent, legal guardian, or other responsible party, I attest that all the information provided is complete and accurate. I am aware of the risks associated with getting more than the recommended dose(s). I understand that depending on my immunization history, I may not be considered fully vaccinated. I hereby give my consent to and authorize South Carolina Department of Health and Environmental Control employees and agents to provide immunization services and medical care to me or, in case of a parent or legal guardian, to my child or ward.

Client/Parent/Legal Guardian Signature (if client less than 16 years of age): _____ **Date:** _____

Relationship to Person Receiving Vaccine: _____

Vaccine Name	Dosage	Dose	Site	Route	Lot #	Manufacturer	EUA Fact Sheet
Moderna COVID-19 Vaccine	☐0.5ml ☐0.25ml (booster)	☐1 ☐2 ☐3	☐LA ☐ RA ☐LL ☐ RL	IM		Moderna	☐ Fact sheet provided
Pfizer- BioNTech COVID-19 Vaccine Children 5-11 years of age	☐0.3ml ☐0.2ml	☐1 ☐2 ☐3	☐LA ☐ RA ☐LL ☐ RL	IM		Pfizer	☐Fact sheet provided
Janssen COVID-19 Vaccine	0.5ml	☐1 ☐2	☐LA ☐ RA ☐LL ☐ RL	IM		Janssen	☐Fact sheet provided

Signature/Title of Person Administering Vaccine:	**Date/Time:**
Clinic Site or Health Department:	VAMS Entry Complete: ☐

COVID-19 Vaccination Form
INSTRUCTIONS FOR COMPLETING

Purpose

To provide demographic information, COVID-19 vaccine history, screening, and immunization documentation for administered COVID-19 vaccine in the event of the inability to access the Vaccine Administration Management System (VAMS).

SECTION I*: To be completed by Client or Parent/ Legal Guardian (if client is less than 16 years of age)*

Demographics

- Complete boxes with appropriate information.
- DHEC staff to record assigned MCI number.

Screening.

- Complete screening questions.

Signature

- Sign and date form and indicate relationship to client (if applicable).

SECTION II*: To be completed by DHEC staff*

Documentation

- Complete the dosage, dose number, site, and lot number for the vaccine administered.
- Check the appropriate box in cells where check boxes are available.

Signature and Site (DHEC staff)

- Sign (including title), date, and time the form.
- Record the clinic site/ health department

IIS Entry

- Enter administered vaccine or immune globulin into the VAMS system and check the box to confirm entry.

Office Mechanics

- Forms should be batch filed by year and applicable health record retention schedule (8498 - Adult Comprehensive Health Record and 8499 - Minor Comprehensive Health Record). Records must be maintained in the health department's medical records room or other designated secure area.