
Ce Fiche d’information sur le vaccin pour les bénéficiaires et les soignants comprend la Fiche d’information pour le vaccin Pfizer-BioNTech COVID-19 autorisé pour l’utilisation chez les individus de 5 à 11 ans.

Le vaccin Pfizer-BioNTech COVID-19 a reçu l’Autorisation d’Urgence (EUA) de la FDA pour fournir une série de deux doses à des individus de 5 à 11 ans.

Ce Fiche d’information sur le vaccin contient des informations pour vous aider à comprendre les risques et les avantages du vaccin Pfizer-BioNTech COVID-19 que votre enfant peut recevoir car il y a actuellement une pandémie de COVID-19. Parlez à l’officier du service de vaccination de votre enfant si vous avez des questions.

Cette Fiche peut avoir été mise à jour. Pour la Fiche la plus récente, veuillez consulter www.cvdvaccine.com.

QUOI DE NEUF AVANT QUE VOTRE ENFANT RECÉVEZ CE VACCIN

QUEL EST LE COVID-19 ?
Le COVID-19 est causé par un coronavirus appelé SARS-CoV-2. Vous pouvez attraper le COVID-19 en contact avec une autre personne qui a le virus. C’est une maladie respiratoire qui peut affecter d’autres organes. Les personnes atteintes de COVID-19 ont eu une large gamme de symptômes rapportés, allant de symptômes mineurs à des symptômes graves conduisant à la mort. Les symptômes peuvent apparaître 2 à 14 jours après exposition au virus. Les symptômes peuvent inclure : fièvre ou frissons ; toux ; dyspnée ; fatigue ; douleurs musculaires ou articulaires ; céphalées ; perte de goût ou deodorance ; douleur à la gorge ; congestion ou rhume ; nausées ou vomissements ; diarrhée.

Pour plus d’informations sur l’EUA, voir le "What is an Emergency Use Authorization (EUA)?" section à la fin de cette Fiche d’information sur le vaccin.

1 Vous pouvez recevoir cette Fiche d’information sur le vaccin même si votre enfant est âgé de 12 ans. Les enfants qui feront 11 ans entre leur première et deuxième dose de la série principale peuvent recevoir, pour chaque dose, soit (1) le vaccin Pfizer-BioNTech COVID-19 autorisé pour l’utilisation chez les individus de 5 à 11 ans ; ou (2) COMIRNATY ou l’un des vaccins Pfizer-BioNTech COVID-19 autorisés pour l’utilisation chez les individus de 12 ans et plus.
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](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.

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<th>Website</th>
<th>Fax number</th>
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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](https://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 BEIDES 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.

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<td><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></td>
<td>1-877-829-2619 (1-877-VAX-CO19)</td>
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HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- 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](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.

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LAB-1486-1.0

Revised: 29 October 2021