

# Janssen COVID-19 Vaccine

Fact Sheets and FAQs

Fact Sheet Translations

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On April 23, 2021, the FDA amended the EUA to include information about a very rare and serious type of blood clot in people who receive the vaccine. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

---

## Emergency Use Authorization Status:

Authorized

## Name:

Janssen COVID-19 Vaccine

## Manufacturer:

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

## Authorized Use

For the prevention of coronavirus disease 2019 (COVID-19) for individuals 18 years of age and older

## Common Side Effects

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. [Learn more \(/media/146305/download\)](#).

## Fact Sheets (English) and FAQs

Information	Last Updated
<a href="#">Fact Sheet for Healthcare Providers Administering Vaccine (/media/146304/download)</a>	July 12, 2021
<a href="#">Fact Sheet for Recipients and Caregivers (/media/146305/download)</a>	July 12, 2021
<a href="#">Frequently Asked Questions on the Janssen COVID-19 Vaccine (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions)</a>	April 27, 2021

## Regulatory Information

Information	Date
<a href="#">Concurrence Letter (/media/151141/download)</a> (shelf life extension to 6 months)	July 28, 2021
<a href="#">FDA Decision Memorandum Addendum (/media/150745/download)</a>	July 13, 2021
<a href="#">Concurrence Letter (/media/150743/download)</a>	July 13, 2021
<a href="#">Letter Granting EUA Amendment (/media/150723/download)</a>	July 12, 2021
<a href="#">Concurrence Letter (/media/150136/download)</a> (Reissued)	July 2, 2021
<a href="#">Concurrence Letter (/media/150163/download)</a> (Reissued)	July 2, 2021
<a href="#">Concurrence Letter (/media/150567/download)</a>	July 2, 2021
<a href="#">FDA Decision Memorandum Addendum (/media/150571/download)</a>	July 1, 2021
<a href="#">FDA Decision Memorandum Addendum (/media/150139/download)</a>	June 15, 2021
<a href="#">FDA Decision Memorandum (/media/150081/download)</a>	June 11, 2021
<a href="#">Letter of Authorization (/media/146303/download)</a> (Reissued)	June 10, 2021
<a href="#">Concurrence Letter (/media/150064/download)</a> (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
<a href="#">Letter Granting EUA Amendment (/media/147865/download)</a>	April 23, 2021
<a href="#">Letter Granting EUA Amendment (/media/147194/download)</a>	March 29, 2021

Information	Date
<a href="/media/146338/download">FDA Decision Memorandum (/media/146338/download)</a>	February 27, 2021
<a href="/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-february-26-2021-meeting-announcement">Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-february-26-2021-meeting-announcement)</a>	February 26, 2021

## Media Materials and Webcasts

Information	Date
<a href="/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough">Press Release (/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough)</a>	April 23, 2021
<a href="https://youtu.be/Nf_OuB1rBi0">Joint FDA and CDC Press Conference (https://youtu.be/Nf_OuB1rBi0)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">⏏ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	April 23, 2021
<a href="/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine">Joint CDC and FDA Statement (/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine)</a>	April 13, 2021
<a href="https://youtu.be/_ELXnGYgsJY">Joint FDA and CDC Media Call (https://youtu.be/_ELXnGYgsJY)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">⏏ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	April 13, 2021
<a href="https://youtu.be/m_eSKpm19zk">Media Call (https://youtu.be/m_eSKpm19zk)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">⏏ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	February 27, 2021
<a href="/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine">Press Release (/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine)</a>	February 27, 2021
<a href="https://youtu.be/Qd7mlCD-rEA">Advisory Committee Meeting Webcast (https://youtu.be/Qd7mlCD-rEA)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">⏏ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	February 26, 2021

## Translations of the Fact Sheet for Recipients and Caregivers

Fact Sheet	Language
<a href="/media/146768/download">بيان حقائق لمتلقي ومقدمي الرعاية الصحية (/media/146768/download)</a> (July 12, 2021)	عربي (Arabic)
<a href="/media/146640/download">প্রাপক এবং সেবাপ্রদানকারীদের জন্য তথ্য পত্র (/media/146640/download)</a> (July 12, 2021)	ইংরেজী (Bengali)

Fact Sheet	Language
<a href="/media/146537/download">ကာကွယ်ဆေး လက်ခံရရှိသူများနှင့် စောင့်ရှောက်မှု ပေးသူများအတွက် သတင်းအချက်အလက် စာရွက် (/media/146537/download)</a> (July 12, 2021)	မြန်မာ (Burmese)
<a href="/media/146841/download">ᎠᎵᎠᎵ ᎠᎵᎠᎵ ᎠᎵᎠᎵ ᎠᎵᎠᎵ ᎠᎵᎠᎵ ᎠᎵᎠᎵ (/media/146841/download)</a> (July 12, 2021)	ᎠᎵᎠᎵ (Cherokee)
<a href="/media/146685/download">接受者和护理者须知 (/media/146685/download)</a> (July 12, 2021)	中文 (Chinese, Simplified)
<a href="/media/146686/download">TAROPWEN AFFAT (IKA FACT SHEET) REN CHON ANGEI ME CHON TUMUN (/media/146686/download)</a> (July 12, 2021)	Foosun Chuuk (Chuukese)
<a href="/media/146767/download">برگه اطلاعات برای دریافت کنندگان و ارائه کنندگان مراقبت (/media/146767/download)</a> (July 12, 2021)	فارسی (Farsi)
<a href="/media/146687/download">FICHE D'INFORMATION POUR LES BÉNÉFICIAIRES ET LES AIDANTS (/media/146687/download)</a> (July 12, 2021)	Français (French)
<a href="/media/146538/download">MERKBLATT FÜR EMPFÄNGER UND BETREUER (/media/146538/download)</a> (July 12, 2021)	Deutsch (German)
<a href="/media/146693/download">પ્રાસિકર્તા અને સંભાળ રાખનારાઓ માટે તથ્ય શીટ (/media/146693/download)</a> (July 12, 2021)	ગુજરાતી (Gujarati)
<a href="/media/146838/download">FEY ENFOMASYON POU MOUN K'AP RESEVWA AVEK MOUN K'AP BAY SWEN (/media/146838/download)</a> (July 12, 2021)	Kreyòl Ayisyen (Haitian Creole)
<a href="/media/146696/download">प्राप्तकर्ताओं और देखभाल कर्ताओं के लिए तथ्य पत्र/फैक्ट शीट (/media/146696/download)</a> (July 12, 2021)	हिन्दी (Hindi)
<a href="/media/146738/download">DAIM NTAWV QHIA TSEEB RAU COV NEEG TAU KEV PAB THIAB COV NEEG ZOV TU (/media/146738/download)</a> (July 12, 2021)	Hmoob (Hmong)
<a href="/media/146739/download">SCHEDA INFORMATIVA PER RICEVENTI E ASSISTENTI (/media/146739/download)</a> (July 12, 2021)	Italiano (Italian)
<a href="/media/146740/download">ワクチン接種を受ける人と介護従事者のためのファクトシート (/media/146740/download)</a> (July 12, 2021)	日本 (Japanese)

Fact Sheet	Language
<a href="/media/146699/download">ប្រតិបត្តិការណ៍សម្រាប់អ្នកទទួលនិងអ្នកថែទាំ</a> (/media/146699/download) (July 12, 2021)	ភាសាអង់គ្លេស (Khmer)
<a href="/media/146839/download">환자와 의료진을 위한 정보지</a> (/media/146839/download) (July 12, 2021)	한국어 (Korean)
<a href="/media/146840/download">PEBA IN KÖMELELE ÑAN RO REJ BÖK WĀ IM RO REJ LALE RO RE NAÑINMEJ</a> (/media/146840/download) (July 12, 2021)	Pālle (Marshallese)
<a href="/media/146842/download">BAA ÁDAHWIILYÁNÍÍ DÓÓ BÁ ADAHAZT'I'ÍÍ NAALTSOOS BEE ÉÉHÓZINÍÍ ÁT'É</a> (/media/146842/download) (July 12, 2021)	Bilagáanaa Bizaad jí (Navajo)
<a href="/media/146799/download">ARKUSZ INFORMACYJNY DLA OSÓB SZCZEPIONYCH I ICH OPIEKUNÓW</a> (/media/146799/download) (July 12, 2021)	Polski (Polish)
<a href="/media/146741/download">FICHA TÉCNICA PARA BENEFICIÁRIOS E PROFISSIONAIS DE SAÚDE</a> (/media/146741/download) (July 12, 2021)	Português (Portuguese)
<a href="/media/146539/download">ИНФОРМАЦИОННЫЙ БЮЛЛЕТЕНЬ ДЛЯ РЕЦИПИЕНТОВ И СПЕЦИАЛИСТОВ ПО УХОДУ</a> (/media/146539/download) (July 12, 2021)	Русский (Russian)
<a href="/media/146798/download">XAASHIDA MACLUUMAADKA EE LOOGU TALAGALAY TALLAAL QAATAYAASHA IYO DARYEELAYAASHA</a> (/media/146798/download) (July 12, 2021)	Soomaali (Somali)
<a href="/media/146762/download">HOJA INFORMATIVA PARA RECEPTORES Y PROVEEDORES DE CUIDADO</a> (/media/146762/download) (July 12, 2021)	Español (Spanish)
<a href="/media/146797/download">FACT SHEET PARA SA MGA TATANGGAP AT MGA TAGAPAG-ALAGA</a> (/media/146797/download) (July 12, 2021)	Tagalog (Tagalog)
<a href="/media/146742/download">TỜ THÔNG TIN CHO NGƯỜI NHẬN VÀ NHỮNG NGƯỜI CHĂM SÓC</a> (/media/146742/download) (July 12, 2021)	Tiếng Việt (Vietnamese)
<a href="/media/146796/download">אינפארמאציע בלאט פאר די וועלכע באקומען די וואקסין און פאר געהילפן (גבאים)</a> (/media/146796/download) (July 12, 2021)	יידיש (Yiddish)