



Alaska Maritime Agencies

4341 B Street, Suite 202, Anchorage, AK 99503

Tel: (907) 562-8808 Fax: (907) 782-4110 Email: ancoffice@alaskamaritime.com



COVID-19 VACCINE AVAILABLE TO CREW MEMBERS CALLING AT SOME ALASKA PORTS

Vaccine Information

Alaska Maritime Agencies is pleased to be able to assist with getting vessel crewmembers vaccinated against the COVID-19 / SARS-CoV-2 virus. Given the local supply, and the constraints imposed by vessel scheduling, only the single-shot Johnson and Johnson (Janssen) inoculation is being offered. The other two-shot-series vaccines are not available to crew members at the moment, since vessels cannot guarantee a return to an Alaska port within the specific second-shot window.

Please see the attached Janssen COVID-19 – EUA Fact Sheet for Recipients and Caregivers for more information about this vaccine.

ALAMAR's local, and informal, experience is that individuals that receive this vaccine may have a brief and temporary reaction to the inoculation for about 24 hours after the injection. Crew members that receive the vaccine may feel sick or experience joint pain as the vaccine is incorporated into the body's immune response. Masters should be aware of this as it relates to effective and attentive watch-standing. Our informal experience also suggests that these reactions tend to be more pronounced in younger vaccine recipients, and those who have recovered from a previous case of COVID-19.

In the event that a vaccine recipient is experiencing side effects for beyond the normal 24 to 48-hour period, please submit a report to VAERS, as directed in the attached flyer.

Crew Member Eligibility

CBP Anchorage has dictated that crew members who are uninspected and/or detained on board, are *NOT ELEGIBLE* for medical paroles to go ashore for the purpose of getting vaccinated. However, ALAMAR is pleased to note that we have engaged the services of mobile clinicians who can visit the vessel (in certain ports, and subject to local vaccine inventory) and provide injections to the entire crew, *regardless of visa status*.

Costs and Options

Though technically the cost of the vaccine itself is borne by the State and Federal Government, Western Ocean Services assesses a Tariff Fee of 170 USD per vaccinated crew member. This cost is to cover the labor associated with:

- Coordination and execution of the vaccination event.
- Submission of crew manifests prior to the vaccination event.
- Providing TWIC escorts to medical staff through Port Security.
- Obtaining special permission from CBP to allow non-cargo-essential personnel to board the vessel prior to-, or in the absence of-, a CBP vessel inspection.
- Providing visiting medical personnel with port-required non-medical industrial PPE.
- Management of any resultant documentation from the event.

Should a vessel wish to decline a vaccination event for all (or most) of the crew, we can arrange for CBP-inspected individuals with valid C1/D or B Visas to get vaccinated ashore. The cost will be the same as above, plus associated ground transportation costs.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen 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 receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine 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 Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

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. Common 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 JANSSEN COVID-19 VACCINE?

The Janssen 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 Janssen 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.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

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

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: 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.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen COVID-19 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 Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

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

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you 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 “Janssen COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

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

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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 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 GET THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Currently, there is no FDA approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?


No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com .	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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 VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. 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, 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 TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURE 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 for 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)?

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The 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 Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and 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 during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA



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For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

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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: 02/2021

VAERS

Vaccine Adverse Event Reporting System

A National Program for Monitoring Vaccine Safety

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS), is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and reviews reports of adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed.

VAERS provides valuable information

VAERS is an early-warning system that detects problems possibly related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important information to identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate reports of adverse events

VAERS defines a "serious adverse event" as life-threatening illness, hospitalization, prolongation of an existing hospitalization, permanent disability or death. Once adverse events are identified using VAERS, they may be monitored in other immunization safety systems to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. CDC and FDA encourage anyone who experiences an adverse event after receiving a vaccine to report to VAERS.

How to report to VAERS

You can report to VAERS online at <https://vaers.hhs.gov/index>.

For further assistance reporting to VAERS, visit <https://vaers.hhs.gov/index> or contact VAERS directly at info@VAERS.org or 1-800-822-7967.

VAERS data are available to the public

VAERS data can be downloaded at <https://vaers.hhs.gov/data/index> or searched at <http://wonder.cdc.gov/vaers.html>. Privacy is protected and personal identifying information (such as name, date of birth and address) is removed from the public data.

*Healthcare providers are encouraged to report all clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event. They are also required to report to VAERS adverse events found in the Reportable Events Table (RET) at https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf



For more information about VAERS:

E-mail: info@vaers.org

Phone: 1-800-822-7967

Web site: www.vaers.hhs.gov



FACT SHEET

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