



# GHC Covid-19 Vaccine Information

## V SAFE

- Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose
- Use your smartphone's browser to go to [v.safe.cdc.gov](https://v.safe.cdc.gov)



## VACCINE CHOICE

- Girdwood Health clinic will be administering Moderna vaccine due to storage and handling requirements. The Moderna EUA and Fact sheet are included in this packet.
- There are other Covid-19 Vaccine choices available, for information see the links below:
  - Pfizer.com
  - [www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html)
  - [www.fda.gov/media/144414/download](https://www.fda.gov/media/144414/download) (EUA Fact sheet for Pfizer Vaccine)

## THINGS TO KNOW ABOUT MODERNA

- EUA approval for 18 and older
- Contraindication: The Moderna Covid-19 Vaccine should not be administered to individuals with a known history of severe allergic reaction to any component of the Moderna Covid-19 Vaccine.

- Immunocompromised persons including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna Covid-19 Vaccine.
- Pregnancy: Available data on Moderna Vaccine administered to Pregnant women are insufficient to inform vaccine associated risk in pregnancy. Please see your healthcare provider to make an informed decision.
- Lactation: Data are not available to assess the effects of Moderna Covid-19 vaccine on the breastfed infant or on production/excretion. Please see your healthcare provider to make an informed decision.
- Pregnant women who are vaccinated with Moderna Covid-19 Vaccine are encouraged to enroll in the registry by calling 1-866-663-3762

## 2<sup>ND</sup> DOSE

- GHC can **only** offer 2<sup>nd</sup> doses exactly 28 days after your first dose. While we recognize there is a grace period per the CDC, our 2<sup>nd</sup> dose appointments have been built in order to maintain clinic operations.
- By receiving your first dose at GHC, you are agreeing to receive your second dose 28 days later.



**Girdwood Health Clinic  
Registration and Informed Consent for COVID-19 Immunization**

Date: \_\_\_\_\_ Emergency Use Authorization Fact Sheet received?  Yes  No

**PARTICIPANT'S INFORMATION**

First Name	Middle Initial	Last Name
Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other	
Date of Birth	Age	
Mailing Address: Street, City, State, Zip		
Cell Phone	Home Phone	
Race	<input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> Other	
Check all that apply	<input type="checkbox"/> Black/African American <input type="checkbox"/> Hawaiian/Pacific Islander <input type="checkbox"/> Decline	
Hispanic?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Decline	
Insurance Type	<input type="checkbox"/> Medicaid <input type="checkbox"/> Medicare <input type="checkbox"/> Tricare <input type="checkbox"/> Other Private Insurance <input type="checkbox"/> Uninsured	

**Do you have any of the following Health Conditions? Asthma - Serious Heart Condition - Liver Disease - Chronic Lung Disease - Diabetes - Severe Obesity - Immunocompromised**  Yes  No  Unknown

**Occupation**

<input type="checkbox"/> Construction, Landscaping, Other trades <input type="checkbox"/> First Responders-Fire, Police, EMT <input type="checkbox"/> Healthcare-Direct Patient contact <input type="checkbox"/> Healthcare-No direct Patient contact <input type="checkbox"/> Office worker-manager, supervisor, employee, clerical <input type="checkbox"/> Oil Industry <input type="checkbox"/> Plant workers, Manufacturing, Machine Operators, and assemblers <input type="checkbox"/> School employee or contractor	<input type="checkbox"/> Seafood Industry <input type="checkbox"/> Service-entertainment <input type="checkbox"/> Service- Restaurants, Bars, Catering, Fast Food <input type="checkbox"/> Service- Retail, cosmetology, massage, elective services <input type="checkbox"/> Service- Transportation <input type="checkbox"/> Service- Tourism <input type="checkbox"/> Skilled Agriculture <input type="checkbox"/> Other
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<b>Prevaccination Checklist for Covid-19 Vaccine</b>			
<b>The following questions will help us determine if there is any reason you should not get the Covid-19 vaccine today. If you answer "yes" to any questions it does not mean you should not be vaccinated. It just means additional questions may be asked.</b>	YES	NO	Don't Know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine? • If yes, which vaccine product did you receive? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Another product			
3. Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
• A component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for a colonoscopy			
• Polysorbate			
• A previous dose of COVID-19 vaccine			
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			

5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would include food, pet, environmental, or oral medication allergies.			
6. Have you received any vaccine in the last 14 days?			
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
10. Do you have a bleeding disorder or are you taking a blood thinner?			
11. Are you pregnant or breastfeeding?			

**Informed Consent:** *Please read and sign.*

My signature below indicates that:

- I have voluntarily chosen to receive the vaccination and consent to the administration.
- I am of legal age and authorized to execute this consent form or I am the parent/guardian of the minor patient or am authorized to consent on behalf of the client.
- I have read, or have had read to me, the Vaccine Information Statement(s) (“VIS”) or Emergency Use Authorization (“EUA”) provided for the vaccine(s) to be administered.
- I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction.
- I understand the benefits and risks of the vaccine(s).
- I will immediately alert the provider of any medical conditions which may adversely affect my personal health or effectiveness of the vaccine.
- I understand I should remain in the area for 15 minutes after the vaccination for observation or 30 minutes if I have any history of severe allergic reaction or anaphylaxis.

Parent/Guardian/Authorized Representative Print \_\_\_\_\_

Parent/Guardian/Authorized Rep. Signature \_\_\_\_\_ Date \_\_\_\_\_

**OFFICE USE ONLY**

Vaccine	1 <sup>st</sup> /2 <sup>nd</sup> dose	VFC/AVAP	Admin Site	Lot #	Manufacturer	EUA Fact Sheet Date
Moderna COVID-19 vaccine 0.5 mL		V07			MOD	

Record Card provided to patient      Provider name (Print) \_\_\_\_\_  
 Provider name (Signature) \_\_\_\_\_

Adverse Event \_\_\_\_\_       VAERS Report completed \_\_\_\_\_  
 \*Adverse Event Type     Local     Syncope     Anaphylaxis  
 \*(If there was an adverse event, an event type must be selected.)

Arrival Time \_\_\_\_\_ Exit Time \_\_\_\_\_

Administration Sites	
Left Deltoid IM	LDI
Right Deltoid IM	RDI

EHR: \_\_\_\_\_ VacTrAK: \_\_\_\_\_ Next Dose: \_\_\_\_\_

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS**  
**EMERGENCY USE AUTHORIZATION (EUA) OF**  
**THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019**  
**(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER**

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

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

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

**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. 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 MODERNA COVID-19 VACCINE?**

The Moderna 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 Moderna 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 MODERNA COVID-19 VACCINE?**

Tell your 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 MODERNA COVID-19 VACCINE?**

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

## **WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?**

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

- 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 MODERNA COVID-19 VACCINE?**

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

## **HOW IS THE MODERNA COVID-19 VACCINE GIVEN?**

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

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

## **HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?**

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

## **WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?**

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

## WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

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

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna 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 Moderna 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

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna 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 “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

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](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?**

It is your choice to receive or not receive the Moderna 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 MODERNA 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 MODERNA COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Moderna 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 MODERNA COVID-19 VACCINE GIVE ME COVID-19?**

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


**KEEP YOUR VACCINATION CARD**

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

**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.

<b>Moderna COVID-19 Vaccine website</b>	<b>Telephone number</b>
<a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a> 	1-866-MODERNA (1-866-663-3762)

**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 state or local 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. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

### **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/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

### **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

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

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)

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