VACCINE INFORMATION STATEMENT

COVID-19 Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See <u>www.immunize.org/vis</u>

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite <u>www.immunize.org/vis</u>

1. Why get vaccinated?

COVID-19 vaccine can prevent **COVID-19** disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can cause mild to moderate illness lasting only a few days, or severe illness requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can result in death.

If an infected person has symptoms, they may appear 2 to 14 days after exposure to the virus. Anyone can have mild to severe symptoms.

- Possible symptoms include fever or chills, cough, shortness of breath or difficulty breathing, fatigue (tiredness), muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea.
- More serious symptoms can include trouble breathing, persistent pain or pressure in the chest, new confusion, inability to wake or stay awake, or pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone.

Older adults and people with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick from COVID-19.

2. COVID-19 vaccine

Updated (2023–2024 Formula) COVID-19 vaccine is recommended for everyone 6 months of age and older.

COVID-19 vaccines for infants and children 6 months through 11 years of age are available under Emergency Use Authorization from the U. S. Food and Drug Administration (FDA). Please refer to the Fact Sheets for Recipients and Caregivers for more information. For people 12 years of age and older, updated COVID-19 vaccines, manufactured by ModernaTX, Inc. or Pfizer, Inc., are approved by FDA.

- Everyone 12 years and older should get 1 dose of an FDA-approved, updated 2023–2024 COVID-19 vaccine. If you have received a COVID-19 vaccine recently, you should wait at least 8 weeks after your most recent dose to get the updated 2023–2024 COVID-19 vaccine.
- Certain people who have medical conditions or are taking medications that affect the immune system may get additional doses of COVID-19 vaccine. Your health care provider can advise you.

Some people 12 years of age and older might get a different COVID-19 vaccine called Novavax COVID-19 Vaccine, Adjuvanted (2023–2024 Formula) instead. This vaccine is available under Emergency Use Authorization from FDA. Please refer to the Fact Sheet for Recipients and Caregivers for more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of COVID-19 vaccine or an ingredient in the COVID-19 vaccine, or has any severe, lifethreatening allergies
- Has had **myocarditis** (inflammation of the heart muscle) or **pericarditis** (inflammation of the lining outside of the heart)
- Has had **multisystem inflammatory syndrome** (called MIS-C in children and MIS-A in adults)
- Has a weakened immune system

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit.



U.S. Department of Health and Human Services Centers for Disease Control and Prevention People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover. People with current COVID-19 infection should wait to get vaccinated until they have recovered from their illness and discontinued isolation.

Pregnant people with COVID-19 are at increased risk for severe illness. COVID-19 vaccination is recommended for people who are pregnant, breastfeeding, or trying to get pregnant now, or who might become pregnant in the future.

COVID-19 vaccine may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

- Pain, swelling, or redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. This risk has been observed most commonly in males 12 through 39 years of age. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

See MDHHS Addendums on next page

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <u>www.vaers.hhs.gov</u> or call **1-800-822-7967**. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

6. 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 the program's website at <u>www.hrsa.gov/cicp</u>, or call **1-855-266-2427**.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for COVID-19 Fact Sheets, package inserts, and additional information at www.fda.gov/vaccines-blood-biologics/industrybiologics/coronavirus-covid-19-cber-regulatedbiologics.
- Contact the Centers for Disease Control and Prevention (CDC):
- Call **1-800-232-4636** (**1-800-CDC-INFO**) or
- Visit CDC's COVID-19 vaccines website at <u>www.cdc.gov/coronavirus</u>.





MDHHS Addendums:

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

The mRNA vaccines (those by Pfizer and Moderna) did not use a fetal cell line to produce or manufacture the vaccine. However, a fetal cell line was used in a very early phase to confirm efficacy prior to production and manufacturing.

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