

HONOR COMMUNITY HEALTH COVID-19 Janssen Vaccine FAQ'S Info Packet



461 W Huron St # 107, Pontiac, MI 48341

Is this vaccine safe?

Yes. The Michigan Department of Health and Human Services (MDHHS) has stated the following: "The process used to approve the COVID-19 vaccines is the same proven process that was used to create safe and effective vaccines for the flu, polio, measles, whooping cough, and more. While the COVID-19 vaccines are being developed as quickly as possible, routine processes and procedures remain in place to ensure the safety of any vaccine authorized or approved for use."

The vaccines were developed very quickly. Were all the usual safety steps taken?

Yes! There were no safety steps skipped in the development of the vaccines. Some steps were done simultaneously, and certain characteristics of mRNA vaccines – like Pfizer's and Moderna's – make production quicker and easier.

Do the vaccines alter my DNA?

No. These vaccines are not able to alter DNA. The vaccines do not affect or interact with your DNA in any way.

Is there a cost to get vaccinated?

For vaccinations given at an office visit, your insurance may be billed a small administration fee but will not result in a cost to you. The vaccine itself will be given at no cost.

What are some of the adverse effects after receiving this vaccine?

Headache, fatigue, fever, joint pains, redness, or pain at the site of injection.

How effective are the vaccines, and when would I be protected?

The Pfizer vaccine is 95% effective 7 days after the second dose, and the Moderna vaccine is 94.1% effective 14 days after the second dose. The Johnson & Johnson vaccine is 66% effective 14 days after the single dose, but 93% effective in preventing severe illness and death from COVID-19.

How long do the adverse effects usually last?

Adverse effects usually last a couple of days or less – if they occur at all.

Congratulations and thank you for receiving the COVID-19 vaccine. You have taken an important step in controlling the COVID-19 pandemic and protecting our community. Now you can be an advocate of the vaccine to family and friends. To help you speak to community members our clinicians and physicians have developed this resource to answer some of the most frequently asked questions and concerns.

Thank you for choosing Honor Community Health. We strive to be your partner in health, which is why we offer a range of comprehensive services open to anyone and everyone – regardless of ability to pay, insurance status, or place of residence. To schedule your visit today, please call (248) 724-7600.

Connect with Honor Community Health

461 W Huron St #107, Pontiac, MI 48341
Call to schedule an appointment **(248) 724-7600**
For more info: www.honorcommunityhealth.org/
Find us on Facebook: @honorcommunityhealth

Does this vaccine contain the COVID-19 virus?

No. This does not contain the COVID-19 virus.

If I do not have any medication allergies, what can I take for pain or fever after getting this vaccine?

Acetaminophen (e.g. Tylenol) or ibuprofen (e.g. Motrin).

Does my second dose have to be the same vaccine brand (Pfizer, Moderna, etc.) as my first dose?

At this time, it is required that you receive the same brand for both doses of Pfizer and Moderna vaccines. The Johnson & Johnson vaccine does not require a second dose.

Do I have to return to the same health center to receive my second dose?

For Pfizer and Moderna vaccines, yes. It is important that you return to the same location for your second dose to ensure supply is available and documentation is accurate. The Johnson & Johnson vaccine does not require a second dose.

I already had COVID-19. Is this vaccine still recommended?

Yes. Current data show that one is not likely to get re-infected by COVID-19 within 90 days of becoming ill the first time. It is not yet known how long natural immunity (protection) from getting and recovering from COVID-19 lasts. This is why it is recommended that you still get the vaccine.

If I have had allergic reactions to medications or food or other vaccinations in the past, can I still get the COVID-19 vaccine?

Yes. Currently, the only absolute reason (contraindication) to not get the COVID-19 vaccine is a severe life-threatening reaction (anaphylaxis) to a previous COVID-19 vaccine dose or ingredient. The vaccines have been given safely to those with allergic reactions and anaphylaxis to other things in the past. Consult your physician with questions and for clarification.

Sign up for V-safe by Scanning the QR code

V-safe is a smartphone-based tool that checks in on you after your COVID-19 vaccination. Your participation helps keep COVID-19 vaccines safe — for you and for everyone.

It takes just a few minutes to register and get started. All you need is your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card.

To register online scan the QR code on the right or go to <https://vsafe.cdc.gov/> to get started today!

Do I still have to wear a mask and socially distance after getting this vaccine?

Yes. While it is probable that you are less likely to asymptotically spread COVID-19 after getting the vaccine, just how much less likely is not yet known. For this reason, it is recommended by the CDC that you continue to wear a mask and social distance.

Am I contagious after getting a Pfizer, Moderna, or Johnson & Johnson vaccine?

No. Because they do not contain COVID-19 or any live virus, you will not become contagious from these vaccines.

Does the vaccine contain any eggs, latex or preservatives?

No. The COVID-19 vaccines currently approved for use do not contain any eggs, preservatives, or latex.

Do we know how long someone is protected against COVID-19 after getting this vaccine?

No. This is currently not known. Moderna has released a statement indicating that immunity is expected to last at least 1 year.

I have heard about the issue with blood clots and the Johnson & Johnson (Janssen) vaccine.

On April 13, 2021, administration of the Janssen vaccine was paused when a very small number of vaccine recipients developed uncommon blood clots with low platelets (thrombosis with thrombocytopenia syndrome, TTS). After in depth analysis of the extremely rare TTS by the US Advisory Committee on Immunization Practices (ACIP), administration of the Janssen vaccine resumed on April 24, 2021. Out of nearly 8 million Janssen vaccine recipients, 15 developed TTS (just under 2 per million). Currently, one is far more likely to contract COVID-19 and be at risk for all its short- and long-term effects, hospitalization, and death, than one is to experience TTS from vaccine.

Can I get the flu shot or any other vaccines on the same day?

No. It is not recommended to get this vaccine at the same time as other vaccines. In fact, it is recommended that you do not get another vaccine 14 days before or after you get doses of the COVID-19 vaccine.



Do I need to quarantine after getting this vaccine?

No. Because this does not contain COVID-19 or any live virus, you will not be contagious and do not need to quarantine.

I have heard about new strains of COVID-19 from the United Kingdom (UK), South Africa, and Brazil. What is known about these new strains of COVID-19? Will the COVID-19 vaccine I am getting protect me against these strains?

Based on information currently known, the new strains seem to be more transmissible, but not necessarily more dangerous, than the original COVID-19 strain. The current COVID-19 vaccines (Pfizer, Moderna, and Johnson & Johnson) should still be effective in preventing severe illness from these new strains. Information on COVID-19 and these new strains is constantly evolving, and these responses reflect the most current information that we know on the date of this writing.

Where can I find more information about other questions I have?

For more information on Frequently Asked Questions, please visit the CDC website: www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html



For more information about the Pfizer vaccine scan the QR code using your smartphone OR visit: <https://www.janssencovid19vaccine.com/for-recipients.html#>



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Contact Us: (248) 724-7600



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What to Expect after Getting a COVID-19 Vaccine

Accessible version: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects may affect your ability to do daily activities, but they should go away in a few days. Some people have no side effects.

Common side effects

On the arm where you got the shot:

- Pain
- Redness
- Swelling

Throughout the rest of your body:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

Helpful tips

If you have pain or discomfort after getting your vaccine, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot:

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

To reduce discomfort from fever:

- Drink plenty of fluids.
- Dress lightly.

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Remember

- Side effects may affect your ability to do daily activities, but they should go away in a few days.
- With some COVID-19 vaccines, you will need 2 shots in order to get the most protection. You should get the second shot even if you have side effects after the first shot, unless a vaccination provider or your doctor tells you not to get it.
- You will only need 1 shot of the viral vector COVID-19 vaccine, Johnson & Johnson's Janssen COVID-19 Vaccine.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until about two weeks after your second shot. For COVID-19 vaccines that require 1 shot, it takes about two weeks after vaccination for your body to build protection.
- After you are fully vaccinated, you may be able to start doing some things you had stopped doing because of the pandemic. Visit CDC's website for the latest recommendations. www.cdc.gov/coronavirus/vaccines.



Ask your vaccination provider about getting started with 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 dose

Learn more about v-safe.

www.cdc.gov/vsafe

HEALTHCARE PROVIDER, PLEASE FILL IN THE INFORMATION BELOW:

If your temperature is 101 °F or 38.4 °C or higher or if you have questions, call your healthcare provider.

Tell your healthcare provider about: Severe symptoms, shortness of breath, or high fever, and any symptoms persisting beyond 24 hours

Healthcare provider phone number: Honor Community Health (248) 724-7600

Medication (if needed):

Take 500 mg of Tylenol every 4-6 hours as needed.

(type and dose or amount)



cdc.gov/coronavirus

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.

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 has received EUA from FDA to provide:

- A single dose primary vaccination to individuals 18 years of age and older.
- A single booster dose to individuals 18 years of age and older who have completed a primary vaccination with the Janssen COVID-19 Vaccine.
- A single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine.

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.

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,
- have ever fainted in association with an injection.

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 after a previous dose of this vaccine.
- had a severe allergic reaction to any ingredient of this vaccine.
- had a blood clot along with a low level of platelets (blood cells that help your body stop bleeding) following Janssen COVID-19 Vaccine or following AstraZeneca’s COVID-19 vaccine (not authorized or approved in the United States).

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.

Primary Vaccination

The Janssen COVID-19 Vaccine is administered as a **single dose**.

Booster Dose

- A single booster dose of the Janssen COVID-19 Vaccine may be administered at least two months after primary vaccination with the Janssen COVID-19 Vaccine.
- A single booster dose of the Janssen COVID-19 Vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your health care provider regarding timing of the booster dose.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In clinical trials, more than 61,000 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine. Millions of individuals have received the vaccine under EUA since February 27, 2021.

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

The Janssen COVID-19 Vaccine has been shown to prevent COVID-19. 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.
- Swollen lymph nodes.
- Blood clots.
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).

- Diarrhea, vomiting.

Severe Allergic Reactions

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 with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, 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 after vaccination. Blood clots with low levels of platelets following the Janssen COVID-19 Vaccine have been reported in males and females, across a wide age range of individuals 18 years and older; reporting has been highest in females ages 30 through 49 years (about 1 case for every 100,000 vaccine doses administered), and about 1 out of every 7 cases has been fatal. You should seek medical attention right away if you have any of the following symptoms after receiving the 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.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body’s immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that’s worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

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?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Janssen COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving the Janssen COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

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



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. |
| GDTI: 0886983000363 | |

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 Johnson & Johnson COVID-19 vaccine has been produced by growing the virus in cells of fetal origin during vaccine development and manufacturing (using the PER.C6 line). Such cells were derived from a historic cell line. Even though cells of fetal origin are used to grow the vaccine virus, vaccines do not contain these cells.