

# INFLUENZA VACCINE MRNA

## Influenza Vaccine mRNA

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**Brands:** mFlusiva®

## Introduction

Influenza vaccine mRNA is a mRNA vaccine that stimulates activity immunity to influenza virus infection.<sup>1</sup>

## Uses

### ■ Influenza vaccine, mrna has the following uses:

Influenza vaccine mRNA is indicated for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine.<sup>1</sup> Influenza vaccine mRNA is approved for use in persons 50 years of age and older.<sup>1</sup>

The indication for persons 65 years of age and older is approved under accelerated approval based on immune responses.<sup>1</sup> Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.<sup>1</sup>

## Dosage and Administration

### ■ General

Influenza vaccine mRNA is available in the following dosage form(s) and strength(s):

Influenza vaccine mRNA is an injectable suspension for IM administration.<sup>1</sup> A single dose is 0.38 mL.<sup>1</sup>

### ■ Dosage

It is *essential* that the manufacturer's labeling be consulted for more detailed information on dosage and administration of this drug. Dosage summary:

#### Adults

##### Dosage and Administration

*For IM use.*<sup>1</sup>

*Administer influenza vaccine mRNA as a single 0.38 mL dose.*<sup>1</sup>

## Cautions

### ■ Contraindications

History of severe allergic reaction (e.g., anaphylaxis) to influenza vaccine, mRNA or any of its components.<sup>1</sup>

## ■ Warnings/Precautions

### Management of Acute Allergic Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of influenza vaccine mRNA.<sup>1</sup>

### Guillain-barré Syndrome

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks following previous influenza vaccination, the decision to give influenza vaccine mRNA should be based on careful consideration of the potential benefits and risks.<sup>1</sup>

The 1976 swine influenza vaccine was associated with an increased frequency of GBS.<sup>1</sup> Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than one additional case per 1 million persons vaccinated.<sup>1</sup>

### Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines including influenza vaccine mRNA.<sup>1</sup> Procedures should be in place to avoid injury from fainting.<sup>1</sup>

### Altered Immunocompetence

Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to influenza vaccine mRNA.<sup>1</sup>

### Limitations of Vaccine Effectiveness

Influenza vaccine mRNA may not protect all vaccine recipients.<sup>1</sup>

## Specific Populations

### Pregnancy

*All pregnancies have a risk of birth defect, loss, or other adverse outcomes.<sup>1</sup> In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.<sup>1</sup>*

*Influenza vaccine mRNA is not approved for use in persons younger than 50 years of age.<sup>1</sup> Available data on influenza vaccine mRNA administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.<sup>1</sup>*

*A developmental toxicity study was performed in female rats administered a vaccine containing 100 mcg of nucleoside-modified messenger ribonucleic acid (mRNA; 2.7 times the amount of nucleoside-modified mRNA in a full human dose of influenza vaccine mRNA) twice prior to mating and twice during gestation.<sup>1</sup> The study revealed no evidence of harm to the fetus due to the vaccine.<sup>1</sup>*

### Lactation

*Influenza vaccine mRNA is not approved for use in persons younger than 50 years of age.<sup>1</sup> It is not known whether the vaccine is excreted in human milk.<sup>1</sup> No human or animal data are available to assess the effects of influenza vaccine mRNA on the breastfed infant or on milk production/excretion.<sup>1</sup>*

*The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for influenza vaccine mRNA and any potential adverse effects on the breastfed infant from the vaccine or from the underlying maternal condition.<sup>1</sup> For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.<sup>1</sup>*

### Pediatric Use

*Safety and effectiveness of influenza vaccine mRNA have not been established in persons younger than 18 years of age.<sup>1</sup>*

### Geriatric Use

*Of the 20,350 participants 50 years of age and older who received influenza vaccine mRNA in the principal efficacy study in adults 50 through 64 years of age, 9,726 (47.8%) were 65 years of age and older and 2,354 (11.6%) were 75 years of age and older.<sup>1</sup> Of the 1,502 participants 65 years of age and older who received Moderna mRNA quadrivalent influenza vaccine during the 2023-2024 influenza season in a study in adults 65 years of age and older, 326 (21.7%) were 75 years of age and older.<sup>1</sup>*

## ■ Common Adverse Effects

- In participants 50 through 64 years of age, the most commonly reported ( $\geq 10\%$ ) adverse reactions were injection site pain (68.7%), fatigue (48.1%), headache (41.9%), myalgia (40.6%), arthralgia (31.5%), chills (27.5%), and axillary (underarm) swelling or tenderness (20.3%).<sup>1</sup>,
- In participants 65 years of age and older, the most commonly reported ( $\geq 10\%$ ) adverse reactions were injection site pain (62.9%), fatigue (42.1%), headache (33.7%), myalgia (30.2%), arthralgia (24.1%), chills (18.1%), and axillary (underarm) swelling or tenderness (14.2%).<sup>1</sup>,

## Drug Interactions

### ■ Specific Drugs

It is *essential* that the manufacturer's labeling be consulted for more detailed information on interactions with this drug, including possible dosage adjustments.

Interaction highlights:

Please see product labeling for drug interaction information.

## Actions

### ■ Mechanism of Action

Influenza vaccine mRNA encodes for the full-length hemagglutinin (HA) glycoproteins of the 3 influenza virus strains represented in the vaccine.<sup>1</sup> Each 0.38 mL dose contains three RNAs (12.5 micrograms of each RNA, for a total of 37.5 micrograms of RNA) encapsulated in lipid nanoparticles, each encoding one of the following seasonal influenza strain hemagglutinin (HA) glycoproteins: A/Missouri/11/2025 (H1N1) pdm09-like virus; A/Michigan/105/2025, an A/Darwin/1415/2025 (H3N2)-like virus; and B/Pennsylvania/19/2025, a B/Pennsylvania/14/2025-like virus.<sup>1</sup> After delivery into cells, the mRNA serves as a template for the synthesis of the intended proteins.<sup>1</sup> The expressed, membrane-bound HA glycoproteins of the encoded influenza strains are recognized by immune cells as a foreign antigen, eliciting immune responses, which contribute to protection against influenza.<sup>1</sup>

Antibody against one influenza virus type or subtype confers limited or no protection against another.<sup>1</sup> Furthermore, antibody to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype.<sup>1</sup> Frequent development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual change of one or more new strains in each year's influenza vaccine.<sup>1</sup>

## Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Advise the vaccine recipient or caregiver to read the FDA-approved patient labeling.<sup>1</sup>,
- Inform vaccine recipient or caregiver of the potential benefits and risks of vaccination with influenza vaccine mRNA.<sup>1</sup>,
- Educate vaccine recipient that (1) influenza vaccine mRNA contains mRNA that encodes proteins that cannot cause influenza and (2) influenza vaccine mRNA stimulates the immune system to produce antibodies that help protect against the influenza viruses carrying the proteins contained in the vaccine but does not prevent other respiratory infections.<sup>1</sup>,
- Inform vaccine recipient or caregiver about the potential for adverse reactions.<sup>1</sup>,
- Instruct vaccine recipient or caregiver to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 or [\[Web\]](#).<sup>1</sup>,
- Inform the vaccine recipient that annual vaccination is recommended.<sup>1</sup>,

## Additional Information

AHFS*firstRelease*™. For additional information until a more detailed monograph is developed and published, the manufacturer's labeling should be consulted. It is *essential* that the manufacturer's labeling be consulted for more detailed information on usual uses, dosage and administration, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and acute toxicity.

## Preparations

*Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.*

**Influenza Vaccine mRNA**

| ROUTES     | FORMS                             | STRENGTHS                                                                                                                                                                                                                                       | BRAND NAMES                             | MANUFACTURER |
|------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|
| Parenteral | Injectable suspension, for IM use | Each 0.38 mL dose contains 3 RNAs (12.5 micrograms of each RNA, for a total of 37.5 micrograms of RNA) encapsulated in lipid nanoparticles, each encoding one of the FDA-recommended seasonal influenza virus hemagglutinin (HA) glycoproteins. | Mflusiva 2026-2027 Formula <sup>®</sup> | Moderna US   |

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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**References**

1. Moderna US, Inc. mFLUSIVA<sup>®</sup> (Influenza Vaccine, mRNA) INTRAMUSCULAR prescribing information. 2026 Aug.



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**CONTACT US**

ASHP  
 4500 East-West Highway, Suite 900  
 Bethesda, Maryland 20814  
 Phone: 1-866-279-0681  
 Email: [custserv@ashp.org](mailto:custserv@ashp.org)