

CO-1

FluMist Self/Caregiver Administration

An Innovative Approach to Help Prevent Influenza



Advisory Committee on Immunization Practices (ACIP)
April 15, 2025



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CO-2

Introduction



Allyn Bandell, PharmD

US Medical Lead – Influenza
AstraZeneca

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Innovative Approach to Protect Against Influenza and Reduce Barriers to Help Improve Vaccination Rates

FluMist for Self/Caregiver Administration is same FDA-recommended and approved FluMist vaccine, simply delivered to the home



WHO

Extends the options for who can administer needle-free vaccine

HOW

Enables administration in home settings using established online pharmacy service

WHY

Expands access and empowers individuals to administer FluMist at home according to ACIP recommendations

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Provides Patients a Convenient, Household-Based Option for Flu Vaccination that Increases Flexibility¹

- Builds on increased acceptance of in-home healthcare²
- Recent modeling study found increasing influenza vaccine coverage of school-aged children with caregiver administration of FluMist could result in less spread of flu at home and school¹
- FluMist for self/caregiver administration
 - Provides an option that is easy to self administer
 - Increases access to flu vaccination

1. Williams et al, 2025; 2. McKinsey, Available at www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/pharmacies-new-era-in-the-home

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Safe, Effective Use of FluMist at Home is Based on Well-tested, Trusted Tools and Services



Same FluMist as available in health care provider offices, packaged for delivery and administration by eligible patients



Instructions For Use based on Human Factors/Usability study



“FluMist Home” is an online pharmacy service supporting ordering, delivering, documenting self/caregiver administration



Return shipment program provides materials and instructions to safely dispose of FluMist following use

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FluMist Package Insert and Instructions for Use



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Same Package Insert Whether Administered in Clinic or at Home

- Guides Health Care Providers, adults, and caregivers on eligibility criteria and how to administer
- Details who can administer and receive FluMist
 - Includes specific information regarding self-administration and for administering to individuals 2 to 17 years old
 - Specifies that children should not self-administer
 - Directs self/caregivers to review Instructions for Use

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FluMist for Self/Caregiver Administration Has Been Well Studied

- FDA approved self/caregiver use (2024) building on the original FluMist approval (2003)
- Studies support effectiveness and safety of self/caregiver-administered FluMist

Study	Age	Participants, N	Findings
Ambrose, et al¹	18–64	N = 4561 ▪ Self-administered: 2026 ▪ HCP: 805	<ul style="list-style-type: none"> ▪ Similar effectiveness against flu-like illness, immunogenicity and adverse events ▪ Reactogenicity events comparable
Burgess, et al² Department of Defense	18–49	N = 1077 ▪ Self-administered: 529 ▪ HCP: 548	<ul style="list-style-type: none"> ▪ Immunogenicity did not vary by administration method <ul style="list-style-type: none"> ▪ Similar mean genomic titers for influenza A (H1N1) ▪ 48.7 (SA) vs 45.8 (HCP) p=0.43 ▪ Local and systemic reactogenicity events similar
Jhaveri, et al³	2.6–17.9	N = 27 families, including 41 children ▪ All self-administered	<ul style="list-style-type: none"> ▪ 100% successfully administered FluMist ▪ All adverse events were mild in severity ▪ Some would not have been vaccinated without home access

1. Ambrose CS, Wu X. Vaccine. 2012;31:857–860; 2. Burgess TH et al. Vaccine. 2015;33:3894–3899; 3. Jhaveri R, Allyn K. Clin Ther. 2017;39:204–211.e4

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Instructions for Use Based on Human Factors Usability Studies that Aligned with FDA Guidance¹

Objective

- Confirm intended users can administer FluMist to themselves or to an appropriate child without errors or difficulties that could result in administration failure

Intended Users

- Adult patients aged 18 to 49 years (self-administered)
- Adult caregivers (≥18 years) who administer to adults or children (2-17 years)

Study Recruitment

- Intended to reflect mix of male/female participants, race, educational background, right/left handedness, with or without nasal spray experience

1. Application of Human Factors Engineering Principles for Combination Products: Questions and Answers, Guidance for Industry and FDA Staff, 2023

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Human Factors Usability Final Study Outcomes Confirm FluMist can be Used Safely and Correctly by Intended Users

Study Population

- Included eligible adults and caregivers
- Representative of intended users for FluMist for SA
- Demographics balanced between adult patients and caregivers

Results

Evaluation	Results
Simulated Use	100% of intended users (30/30) demonstrated ability to deliver full dose of FluMist without introducing patterns of use errors or difficulties that could result in vaccination failure or misadministration
Label Comprehension	100% of intended users (30/30) demonstrated ability to successfully read and understand all critical information in instructions for use

Individual user group sample sizes based on FDA guidance

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Final Packaging and Instructions Used in Human Factors Studies Included in sBLA Submitted to FDA

Top of Package



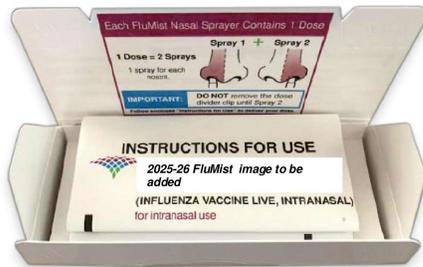
INSTRUCTIONS FOR USE
FluMist® (FLEW-mist)
(Influenza Vaccine Live, Intranasal)
Nasal Spray

This Instructions for Use contains information on how to use FluMist. Even if you have previously used FluMist, there may be new information. This information does not take the place of talking to a healthcare provider about whether to use FluMist.

If you or your caregiver have any questions, talk to a healthcare provider or call MedImmune information center 1-877-633-4411.

Unfold to view full Instructions for Use

View Once Top Is Lifted



Each FluMist Nasal Sprayer Contains 1 Dose (2 Sprays)

1 Dose = 2 Sprays
1 spray for each nostril.

Spray 1 + Spray 2

IMPORTANT: DO NOT remove the dose divider clip until **Spray 2** (Step 9).

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Guidance on How to Open and Inspect Package Before Self-Administration or Administration to Others

Preparing to Use FluMist

- Step 1**
Remove the FluMist carton from the refrigerator and place on a clean flat surface.
• Use FluMist within 12 hours of removing from the refrigerator.
- Step 2**
Check the carton.
• DO NOT use FluMist if the expiration (EXP) date has passed.
• DO NOT use if the carton has been opened, damaged, or appears tampered with.
- Step 3**
Open the carton and remove the FluMist sprayer by holding onto the sprayer body.
• DO NOT hold the sprayer by any other parts.
- Step 4**
Check the FluMist sprayer.
• DO NOT use FluMist if the expiration (EXP) date on the label has passed or if the sprayer appears damaged.
Check the liquid in the sprayer.
• The liquid should be colorless to pale yellow and clear to slightly cloudy.
• DO NOT use if the liquid appears discolored.
• DO NOT attempt to remove bubbles from the sprayer.

- Guidance on amount of time out of refrigerator
 - Within 12 hours
- Items to check upon opening
 - Expiration date
 - Damage to package
 - Color of liquid in sprayer

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Step-by-Step Instructions for Using the Sprayer in Each Nostril

Spray 1		Spray 2	
5	 <p>Step 5</p> <p>Hold on to the sprayer body and pull off the gray cap.</p> <ul style="list-style-type: none"> DO NOT remove the dose divider clip until Step 9. DO NOT push or pull the plunger. DO NOT prime or remove bubbles from the sprayer. DO NOT insert the sprayer into nostril before removing the cap. 	9	 <p>Step 9</p> <p>Holding onto the sprayer body, pinch and remove the dose divider clip from plunger.</p> <ul style="list-style-type: none"> DO NOT push or pull the plunger.
6	 <p>Step 6</p> <p>Keeping head in upright position, place just the sprayer tip inside one nostril. The sprayer tip does not need to be inserted far into the nose.</p> <ul style="list-style-type: none"> DO NOT insert the entire white tip inside the nostril. 	10	 <p>Step 10</p> <p>Keeping head in upright position, place just the sprayer tip inside the other nostril. The sprayer tip does not need to be inserted far into the nose.</p> <ul style="list-style-type: none"> DO NOT insert the entire white tip inside the nostril.
7	 <p>Step 7</p> <p>Administer Spray 1 by pushing the plunger as quickly as possible until it stops at the dose divider clip.</p> <ul style="list-style-type: none"> DO NOT remove sprayer until the plunger has stopped. DO NOT remove the dose divider clip until Step 9. Breathe normally. There is no need to inhale or sniff. It is normal if you feel a slight tickle or experience some dripping or sneezing. 	11	 <p>Step 11</p> <p>Administer Spray 2 by pushing the plunger as quickly as possible until it stops.</p> <ul style="list-style-type: none"> DO NOT remove sprayer until the plunger has stopped. Breathe normally. There is no need to inhale or sniff. It is normal if you feel a slight tickle or experience some dripping or sneezing.
8	 <p>Step 8</p> <p>Remove the sprayer from the first nostril.</p> <ul style="list-style-type: none"> Wipe away any liquid that drips from the nose with a tissue. <p>IMPORTANT: Continue to Spray 2 (Step 9) to remove the dose divider clip.</p>	12	 <p>Step 12</p> <p>Remove the sprayer from the second nostril.</p> <ul style="list-style-type: none"> Wipe away any liquid that drips from the nose with a tissue.
		 <p>Step 13</p> <p>Dispose of used sprayer through return shipment program. Follow the return shipment program steps outlined in the separate directions that were provided with your FluMist dose.</p> <ul style="list-style-type: none"> FluMist contains a single dose and cannot be reused. DO NOT dispose of your used sprayer in your household trash. <p>If you or your caregiver have any questions, talk to your healthcare provider or call 1-877-633-4411. Manufactured by: MedImmune, LLC, Gaithersburg, MD 20878 U.S. Government License No. 1789</p>	

Online Pharmacy Service Fully Supports Patients Interested in Administering FluMist at Home



AstraZeneca and Pharmacy Partner Adhering to Standard Roles

AstraZeneca

- ✓ Manufacture and supply vaccine
- ✓ Develop and launch education and awareness campaigns for patients and health care providers
- ✓ Provide service and support for anyone with FluMist questions

ASPN (Online pharmacy partner)

- ✓ Confirm patient eligibility
- ✓ If eligible, pharmacist writes prescription
- ✓ Manages dispensing and delivery responsibilities
- ✓ Provide pharmacist counseling and support
- ✓ Comply with state rules and regulations based on shipping address

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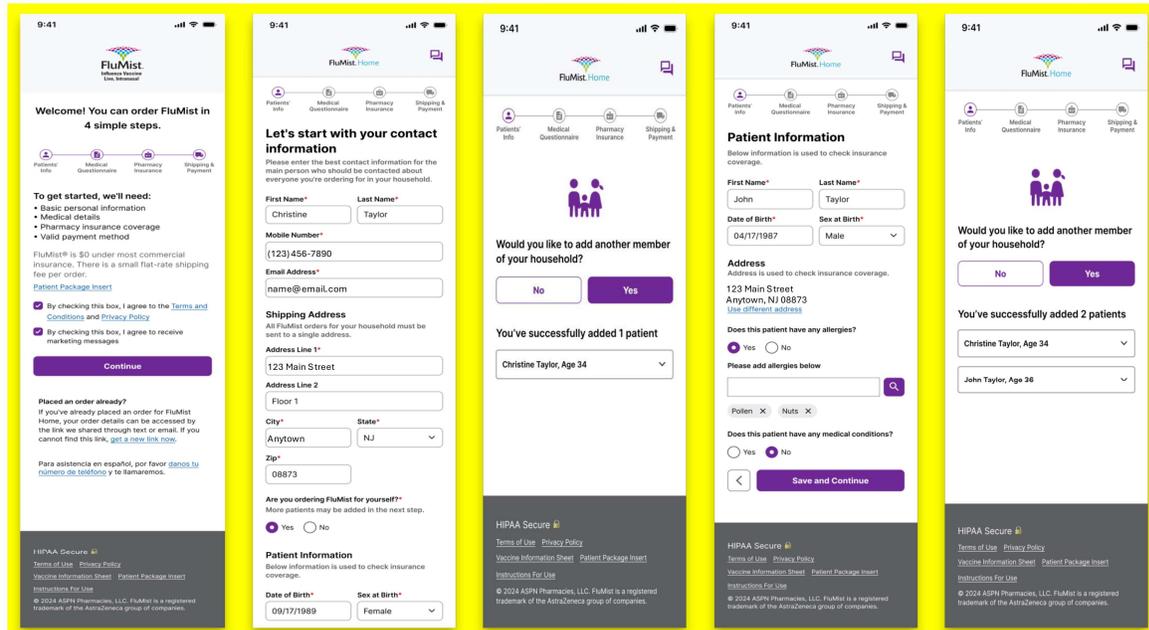
Online Pharmacy Experience Familiar to Patients: Similar to Interfaces Routinely Used by Major Retail Pharmacies

- 1 Enter User Information
- 2 Answer Eligibility Questions
- 3 Share Insurance Information
- 4 Enter Shipping, Payment Information*
- 5 Submit Order

* Delivery fee will be between \$5-\$10/order

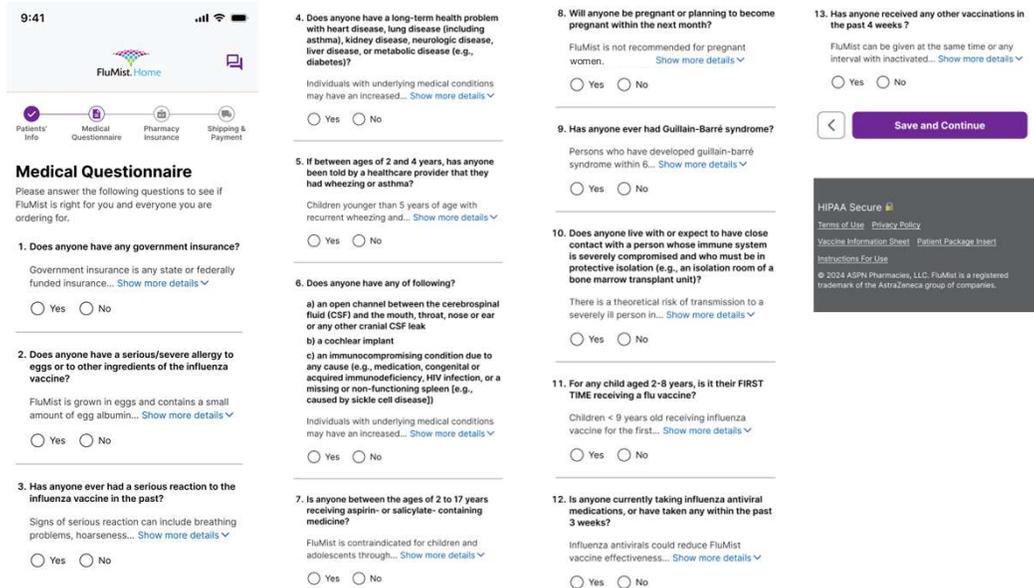
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Adult Household Member Enters Information



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Patients Answer Yes/No Questions Aligned with Flu ACIP Recommendations Allowing Pharmacists to Determine Eligibility



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Patients Answer Yes/No Questions Aligned with Flu ACIP Recommendations Allowing Pharmacists to Determine Eligibility

The screenshot shows the 'Medical Questionnaire' section of the FluMist Home app. The interface includes a progress bar at the top with steps: Patients' Info, Medical Questionnaire, Pharmacy Insurance, and Shipping & Payment. The 'Medical Questionnaire' section contains several questions with 'Yes' and 'No' radio button options. Three callout boxes are overlaid on the screen:

- Callout 1 (Question 2):** "2. Does anyone have a serious/severe allergy to eggs or to other ingredients of the influenza vaccine? FluMist is grown in eggs and contains a small amount of egg albumin... Show more details" with Yes/No options.
- Callout 2 (Question 7):** "7. Is anyone between the ages of 2 to 17 years receiving aspirin- or salicylate- containing medicine? FluMist is contraindicated for children and adolescents through... Show more details" with Yes/No options.
- Callout 3 (Question 10):** "10. Does anyone live with or expect to have close contact with a person whose immune system is severely compromised and who must be in protective isolation (e.g., an isolation room of a bone marrow transplant unit)? There is a theoretical risk of transmission to a severely ill person in... Show more details" with Yes/No options.

Other visible questions include: 1. Government insurance, 3. Serious reaction to influenza vaccine, 4. Long-term health problems, 5. Wheezing/asthma, 6. Various medical conditions, 8. Pregnancy, 9. Guillain-Barré syndrome, 11. Child receiving vaccine for the first time, 12. Current medications, and 13. Other vaccinations.

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Patients Answer Yes/No Questions Aligned with Flu ACIP Recommendations Allowing Pharmacists to Determine Eligibility

The screenshot shows the 'Medical Questionnaire' section of the FluMist Home app. The interface includes a progress bar at the top with steps: Patients' Info, Medical Questionnaire, Pharmacy Insurance, and Shipping & Payment. The 'Medical Questionnaire' section contains several questions with 'Yes' and 'No' radio button options. Two callout boxes are overlaid on the screen:

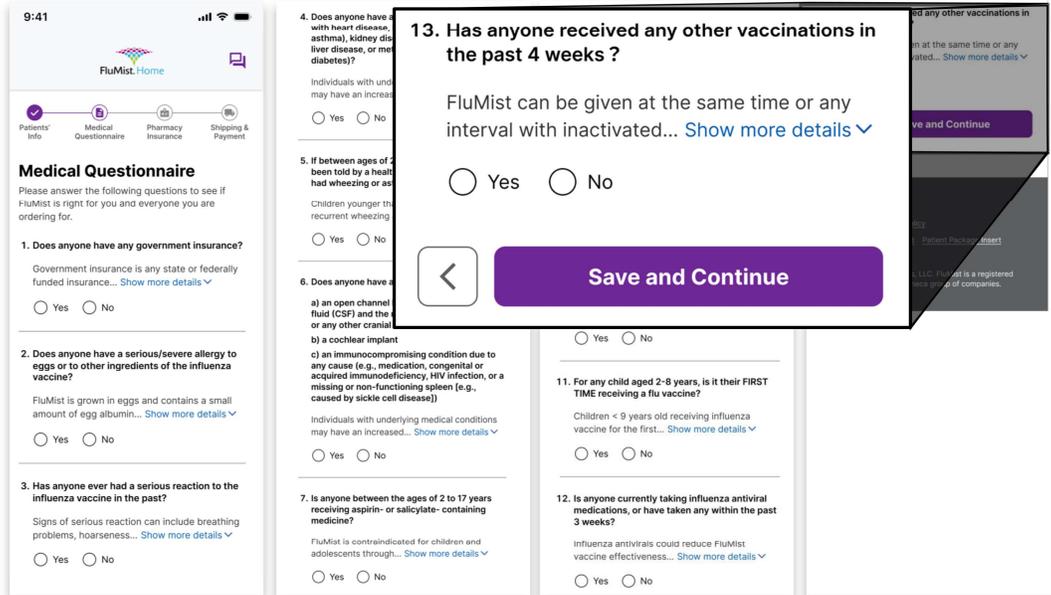
- Callout 1 (Question 10):** "10. Does anyone live with or expect to have close contact with a person whose immune system is severely compromised and who must be in protective isolation (e.g., an isolation room of a bone marrow transplant unit)? There is a theoretical risk of transmission to a severely ill person in... Show more details" with Yes/No options.
- Callout 2 (Question 11):** "11. For any child aged 2-8 years, is it their FIRST TIME receiving a flu vaccine? Children < 9 years old receiving influenza vaccine for the first... Show more details" with Yes/No options.

Other visible questions include: 1. Government insurance, 2. Allergy to ingredients, 3. Serious reaction to influenza vaccine, 4. Long-term health problems, 5. Wheezing/asthma, 6. Various medical conditions, 7. Aspirin/salicylate use, 8. Pregnancy, 9. Guillain-Barré syndrome, 12. Current medications, and 13. Other vaccinations.

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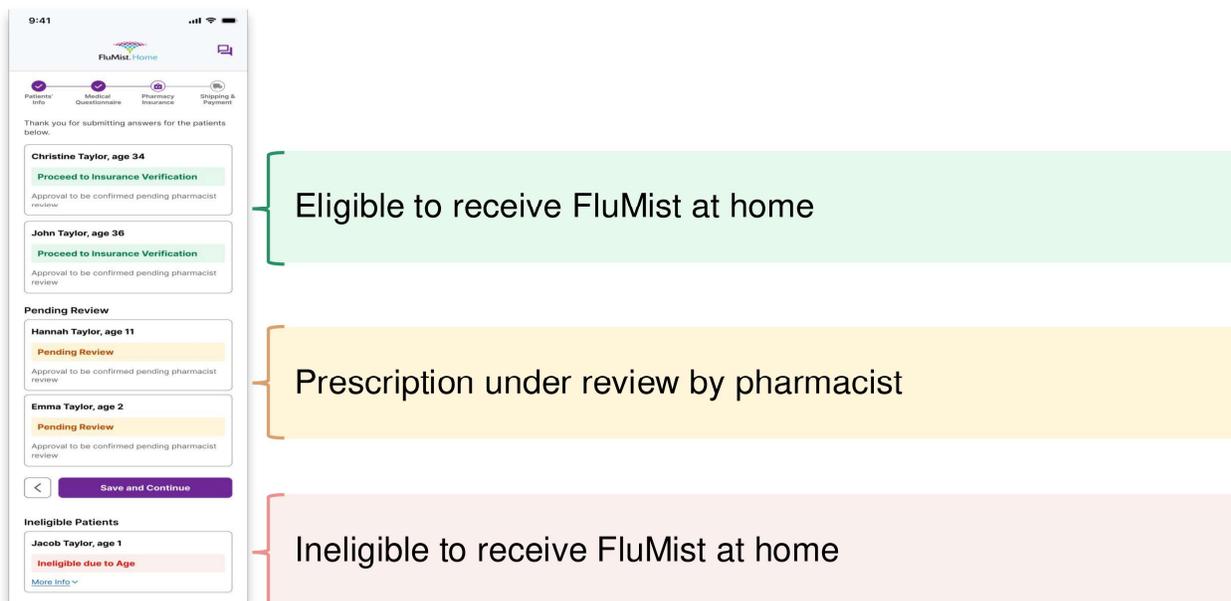
Patients Answer Yes/No Questions Aligned with Flu ACIP Recommendations Allowing Pharmacists to Determine Eligibility



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Patients Notified of Eligibility Based on Responses to Medical Questionnaire



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If “Yes” to a Medical Eligibility Screening Question

The screenshot shows the 'Medical Questionnaire' section of the FluMist.Home app. Question 5 is highlighted with a callout box:

5. If between ages of 2 and 4 years, has anyone been told by a healthcare provider that they had wheezing or asthma?

Children younger than 5 years of age with recurrent wheezing and... Show more details

Yes No

The callout box also contains explanatory text: "Children younger than 5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following administration of FluMist. ACIP guidance specifies wheezing with the last 12 months. It is recommended to consult with your physician prior to taking an influenza vaccine." Below this, it asks "In the past 12 months, who has been told by a healthcare provider that they had wheezing or asthma?" with a dropdown menu showing "Emma Taylor" selected.

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Adult Enters Information to Confirm Pharmacy Coverage

The screenshot shows the 'Insurance Summary' screen in the FluMist.Home app. It lists three individuals:

- Christine Taylor, age 34** (Member ID: W237948273) - Covered by insurance, \$0 copay.
- John Taylor, age 36** (Member ID: W248249583) - Covered by insurance, \$0 copay.
- Hannah Taylor, age 11** - Coverage Pending.
- Emma Taylor, age 2** - Coverage Pending.

Each entry has a 'Remove from order' link. At the bottom, there is a 'Save and Continue' button.

- During launch year, available through health insurance without option to pay out of pocket
- Insurance review validates patient eligibility information
- FluMist will continue to be available through VFC when administered in provider offices
- AstraZeneca will work with VFC program office to consider how FluMist for self administration could be incorporated for future flu seasons

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Adult Selects Delivery Date, Enters Payment Details

Schedule Delivery

Order Summary

PATIENT INFO [Edit](#)

Christine Taylor, age 34	\$ 0.00
John Taylor, age 36	\$ 0.00
Hannah Taylor, age 11	Pending
Emma Taylor, age 2	Pending
Delivery Fee	\$ 5.00
Total	\$ 5.00

Contact Info

Christine Taylor
(123) 456-7890
name@email.com [Edit](#)

Ship To
Your order can only be shipped to one address.

123 Main Street
Anytown, NJ 08873 [Edit](#)

Delivery Date

Refrigerate your FluMist order as soon as possible after delivery. Keep out of reach of children.

Wed	Thu	Fri	Tue
Oct 25	Oct 26	Oct 27	Oct 31

[Show More Dates](#)

Payment Details

Credit/Debit card

Card Number

Credit/Debit card number

Exp Month Exp Year

Security Code

CVV

Other Payment Methods

Apple Pay Google Pay

[Place Order Now](#)

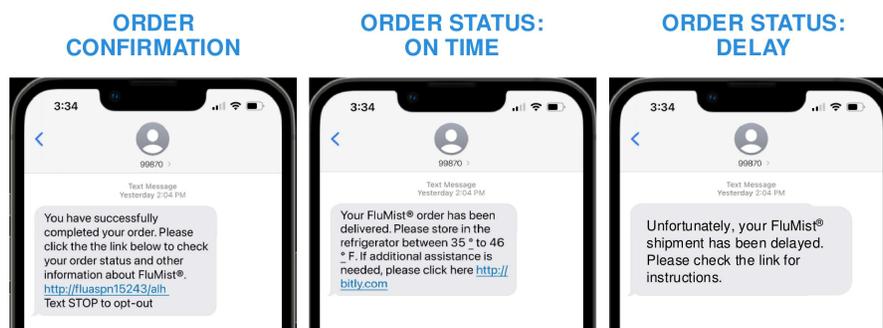
HIPAA Secure [Terms of Use](#) [Privacy Policy](#)
Vaccine Information Sheet [Patient Package Insert](#)
[Instructions For Use](#)
© 2024 GSKVaccines, LLC. FluMist is a registered trademark of the AstraZeneca group of companies.

- Payment covers \$5-10 shipping fee
- Last step is to place order

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FluMist Begins Journey to Arrive at Household on Date Selected; Emails and Text Alerts Track Status

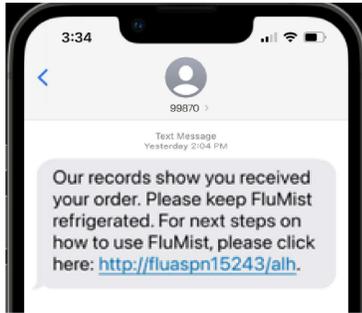


- Text communications include a link to patient portal, where patients can
 - Get additional information
 - Connect with pharmacy

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Instructions for Storing FluMist Before Use Provided Via Text, Email, and Included Inside Package



- Messages provide exact delivery date
- Information sheet visible as soon as package is opened
 - Lists contents, including FluMist devices and cold packs
 - Includes instructions for storing in refrigerator until use
 - Provides multiple ways to access administration instructions
- QR code links to “how-to” videos on website

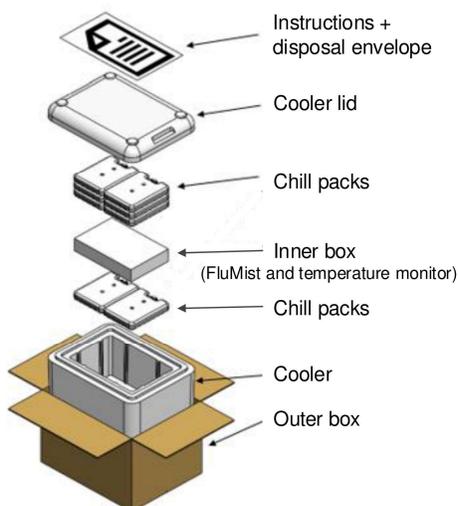


How-to videos not yet available

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Shipping and Handling Process Delivers FluMist to the Right Patient, at the Right Time, at the Right Temperature



- Shipped under strict cold chain procedures using validated storage, packaging, and delivery methods
 - Reviewed, approved by FDA as part of sBLA
- Requires 2-day shipping or less
- Packaging can hold up to 4 FluMist devices
- Includes Vaccine Information Statement (VIS)
- Patients can scan a temperature monitor to confirm vaccine stayed within temperature range during shipping process

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Text Messages Sent to Confirm Administration

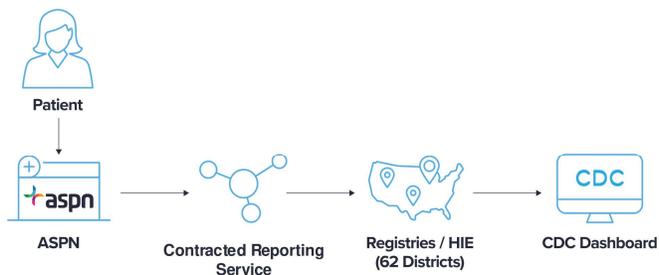


- If patient does not respond
 - Continue to receive reminders
 - Option to reach pharmacist via 800 number or chat
- When patient responds “Yes”
 - Pharmacy reports to Immunization Information System (IIS)
 - Consent is requested when required
 - Pharmacy updates patient’s physician

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Immunization Information System (IIS) Documentation: Uses the Same Reporting Process as Retail Pharmacies

IIS



1. Gather base information as part of patient intake
2. Check if vaccinated
3. Post to Registry
 - Required patient information
 - Pharmacy data (lot #, manufacturer, NDC, VIS date and VIS given date)
 - Optional patient data

Documenting and reporting to medical home

- Pharmacy sends documentation of vaccination when physician information is provided
- Patient portal includes place to download vaccine record to provide to their physician

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Return Shipment Program Ensures Appropriate Disposal



- Return shipment instructions and materials included in FluMist packaging
- Used FluMist devices placed inside prepaid, pre-labeled envelope
 - Holds multiple used FluMist devices
 - Placed into home mailbox
 - Delivered to medical waste company for disposal

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FluMist for Self/Caregiver Administration Offers Flexibility and Opportunities to Increase Vaccination Coverage¹

- FluMist Self/Caregiver option to be available via online pharmacy
- FluMist for HCP administration remains available in clinics, pharmacies
- Ongoing work to advance self/caregiver administration
 - Create materials in additional languages
 - Finalize Phase IV vaccine effectiveness study

Q&A



**Allyn Bandell,
Pharm D**
US Medical Lead, Influenza
AstraZeneca



Andrew Leone
Executive Director
Vaccines and Immune Therapies
AstraZeneca

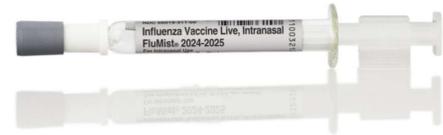


**Ami Patel,
PharmD**
VP, Hub Operations
ASPN

1. Williams et al, 2025

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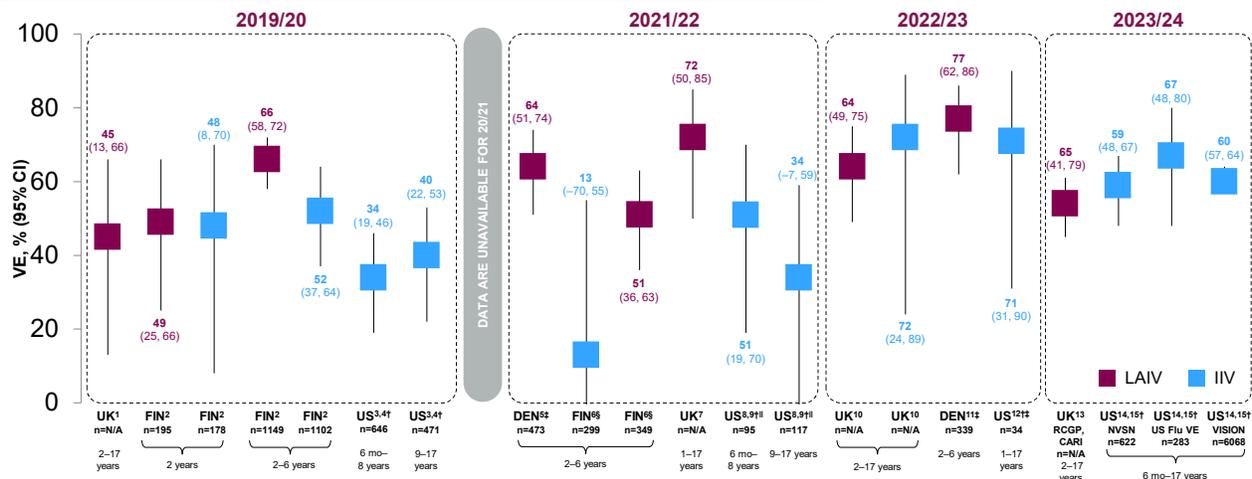
FluMist Self/Caregiver Administration An Innovative Approach to Help Prevent Influenza



Advisory Committee on Immunization Practices (ACIP)
April 15, 2025



Global Vaccine Effectiveness of IIV and LAIV4 in Pediatric Patients – Compilation from Non-Comparative Studies (2019-2024)



Data for FLUMIST Quadrivalent (LAIV4) are relevant to FLUMIST because both vaccines are manufactured using the same process and have overlapping compositions¹⁷

VE CIs truncated at 0 to enable graphical display. †Data for all vaccines, but little use of LAIV4 or IIV3 in the US.^{4,8,15,16} ‡Data for interim influenza A only. §End-of-season estimates from Week 40 (2021) to Week 26 (2022). ¶(H3N2) represented an estimated 94% of all influenza-positive participants. CI = confidence interval; DEN = Denmark; FIN = Finland; GB-PC = Great Britain Primary Care; IV = inactivated influenza vaccine; IIV3 = trivalent inactivated influenza vaccine; LAIV = live attenuated influenza vaccine; LAIV4 = quadrivalent live attenuated influenza vaccine; mo = months; n = total number of cases; N/A = not available; NVSN = New Vaccine Surveillance Network; UK = United Kingdom; US = United States; VE = vaccine effectiveness; VISION = Virtual SARS-CoV-2, Influenza, and Other respiratory viruses Network. 1. Public Health England. Surveillance of influenza and other respiratory viruses in the UK. Winter 2019 to 2020; 2. In-house data, AstraZeneca. DoF 143691; 3. Tenforde MW et al. Article and supplementary appendix. *Clin Infect Dis*. 2021;73(11):e4244-e4250; 4. Committee on Infectious Diseases. *Pediatrics*. 2019;144(4):e20192478; 5. Emborg H et al. *Euro Surveill*. 2022;27(15):220278; 6. In-house data, AstraZeneca. DoF 168928; 7. UK Health Security Agency. Surveillance of influenza and other seasonal respiratory viruses in the UK, winter 2022 to 2023; 11. Kissling E et al. *Euro Surveill*. 2023;28(21):2300116; 12. McLean HQ et al. *MMWR Recomm Rep*. 2023;72(8):201-205; 13. UK Health Security Agency. Surveillance of influenza and other seasonal respiratory viruses in the UK, winter 2023 to 2024; 14. Frutos AM et al. *MMWR Morb Mortal Wkly Rep*. 2024;73(8):168-174; 15. Grohskopf LA, et al. *MMWR Recomm Rep*. 2023;72(2):1-25; 16. Centers for Disease Control and Prevention. Live Attenuated Influenza Vaccine [LAM] (The Nasal Spray Flu Vaccine); 17. FLUMIST Prescribing Information, August 2024.