

LIVE ATTENUATED INFLUENZA VACCINE (LAIV)

FluMist manufactured by MedImmune

Influenza Season 2008 - 2009

POLICY

The Arkansas Department of Health will receive a shipment of FluMist to be used by the local health units in a FluMist Special Initiative. LAIV (FluMist) is licensed for use in non-pregnant, healthy patients ages two (2) through forty-nine (49) years.

PREPARATION

LAIV contains strains of influenza viruses that are equivalent to the annually recommended strains: one influenza A (H3N2) virus, one influenza A (H1N1) virus, and one influenza B virus. The 2008-2009 trivalent vaccine virus strains are A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like, and B/Florida/4/2006- like antigens. The antigens are constituted as live, attenuated, cold-adapted, temperature-sensitive vaccine viruses. Additional components of LAIV include egg allantoic fluid, monosodium glutamate, sucrose, phosphate, and glutamate buffer, and hydrolyzed porcine gelatin. LAIV does not contain thimerosal and is administered intranasally by sprayer.

INDICATIONS

LAIV is intended for intranasal administration only and should not be administered by the intramuscular, intradermal, or intravenous route. LAIV is not licensed for vaccination of children < 2 years or adults > 49 years.

CONTRAINDICATIONS

The effectiveness or safety of LAIV is not known for the following groups, and these persons should not be vaccinated with LAIV:

- persons with a history of hypersensitivity, including anaphylaxis, to eggs, egg proteins, gentamicin, gelatin or arginine or life threatening reaction to previous influenza vaccination
- persons ages <2 years or those ages >49 years;
- persons with any of the underlying medical conditions that serve as an indication for routine influenza vaccination, including asthma, reactive airways disease, or other chronic disorders of the pulmonary or cardiovascular systems; other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies; or known or suspected immunodeficiency diseases or immunosuppressed states;
- children ages 2--4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- children or adolescents receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection);
- persons with a history of Guillain-Barre' Syndrome after a prior influenza vaccination; or
- pregnant women.

NOTE: Screening questions for intranasal influenza vaccination in English and Spanish are included as an attachment.

SPECIAL CONSIDERATIONS

1. Persons who have contact with persons at higher risk for influenza-related complications may receive LAIV.
2. Severely immunosuppressed persons should not administer LAIV. However, other **persons at higher risk for influenza complications can administer LAIV (FluMist)** such as persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged >49 years.
3. People in homeless shelters may not be in good health or be able to provide an accurate history, so those individuals should receive Fluzone (injectable) vaccine, not the live virus in Flu Mist. Therefore, LHUs planning to hold special clinics in homeless shelters should use the Fluzone (injectable) vaccine already in their LHU vaccine inventory. BE SURE to take and complete the other IMM-FLU Form and TIV VIS to document when giving Fluzone instead of FluMist.

DRUG INTERACTIONS

- If not simultaneously administered, FluMist can be administered within 4 weeks of another live vaccine.
- Do not administer FluMist until 48 hours after antiviral cessation
- Antiviral agents should not be administered until 2 weeks after FluMist administration unless medically necessary

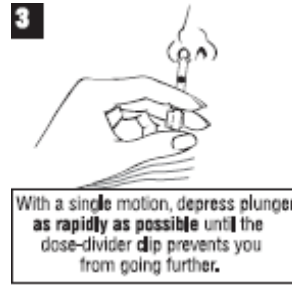
ADVERSE REACTIONS

- runny nose or nasal congestion
- fever > 100°F
- sore throat
- headache
- vomiting
- abdominal pain
- myalgias

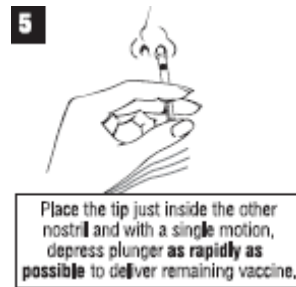
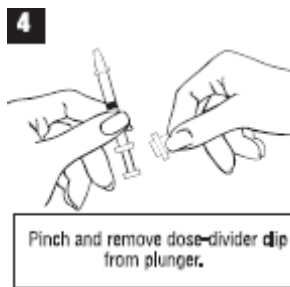
DOSAGE/ADMINISTRATION

LAIV (FluMist) is supplied in a prefilled, single-use sprayer containing 0.2 mL of vaccine. Administer the vaccine according to the following directions:

- Insert the tip of the sprayer just inside the nose and rapidly depress the plunger until the dose-divider stops the plunger which administers approximately 0.1 mL (half of the total sprayer contents) into the first nostril while the recipient is in the upright position



- Remove the attached dose-divider clip from the sprayer to administer the second half of the dose into the other nostril



Note:
Active inhalation (i.e., sniffing) is not required by the patient during FluMist administration.

RECOMMENDATIONS FOR 2ND DOSE

For children ages 2 through 8 years of age who are receiving LAIV (or trivalent inactivated vaccine) for the first time, two doses administered at least 4 weeks apart are recommended. Those children who only received one dose of flu vaccine in any previous influenza season should also receive two doses this year. To notify parents/guardians of the possible need for a second dose, LHU staff should issue the "2008-09 Influenza Vaccine Documentation" which includes information about the 2-dose recommendation.

VACCINE STORAGE/HANDLING

- FluMist is supplied in a package of 10 pre-filled, single-use sprayers
- LAIV is shipped to end users at 35° F - 46°F (2°C-8°C)
- Store at 35°F-46°F (2°C-8°C) upon receipt and maintain at that temperature until the expiration date is reached.
- The sprayer should be disposed of according to the Arkansas Department of Health standard procedures for disposal of medical waste (e.g., sharps container or biohazard container).
- All FluMist for the special initiative expires 1/31/09.

BILLING

- There will be no \$20 charge in any off-site clinics (schools, shelters, churches, business, local government, etc.) where LHU staff is administering FluMist. However, Medicaid and the 2 state insurances will be billed if applicable.
- Billing for FluMist for walk-ins into LHUs should be as appropriate – either \$20, Medicaid, State insurance, no pay, etc. (As FluMist is only for healthy individuals and not for those >49 years of age, there should be no one on Medicare able to take FluMist.)

DOCUMENTATION/MECHANICS/FILING

OFF-SITE CLINICS (Vaccine given by LHU nursing staff)	DOCUMENTATION	MECHANICS/FILING
2 YEARS THROUGH 8 YEARS with one of the designated State Insurances	IMM-FluMist Form	<ul style="list-style-type: none"> • Data enter into INC within 5 days • Make copy and submit to the Immunization Section for data entry of the insurance number • Retain original in LHU Administrative File under Immunizations, marked as "Off-site FluMist Special Initiative 2008-09"
	2008-09 Influenza Vaccine Documentation	<ul style="list-style-type: none"> • Issue to parent/guardian a copy of this form to document influenza vaccine received
2 YEARS THROUGH 8 YEARS without state insurance and for those with Medicaid	IMM-FluMist Form	<ul style="list-style-type: none"> • Data enter into INC within 5 days • No copies required for Immunization Section • Retain form in LHU Administrative File under Immunizations, marked as "Off-site FluMist Special Initiative 2008-09"
	2008-09 Influenza Vaccine Documentation	<ul style="list-style-type: none"> • Issue to parent/guardian a copy of this form to document influenza vaccine received
9 YEARS THROUGH 49 YEARS (includes Medicaid and all others)	IMM-FluMist Form	<ul style="list-style-type: none"> • Submit weekly all original IMM-FluMist forms to the Immunization Section • IMM-FluMist forms will be returned to the LHU by the Immunization Section after data entry • After receipt from Immunization Section, retain in LHU Administrative File under Immunizations, marked as "Off-site FluMist Special Initiative 2008-09"
	2008-09 Influenza Vaccine Documentation	<ul style="list-style-type: none"> • Issue to patient as requested for

		documentation of influenza vaccine received
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NOTE:

- If a FluMist Special Initiative Off-site clinic is sponsored by a school and the vaccine is administered by the school's nursing staff, they should also use the IMM-FluMist Form and the 2008-09 Influenza Vaccine Documentation. The School should make a copy of the IMM-FluMist Form and submit to the Immunization Section for data entering, then maintain the original IMM-FluMist Form for their records. Each school is assigned an Organizational PIN # which should be used in the top left hand corner of the IMM-FluMist Form in "Clinic Code for Providers".
- Use the LHU clinic code when LHU staff is vaccinating in off-site clinics – even if assisting in school clinics. This will be like the mass clinics where non-ADH nurses are considered volunteers.

LHU CLINICS	DOCUMENTATION	MECHANICS/FILING
2 YEARS THROUGH 8 YEARS with one of the designated State Insurances	IMM-FluMist Form	<ul style="list-style-type: none"> • Data enter into INC within 5 days • Make copy and submit to the Immunization Section for data entry of the insurance number • Retain original in LHU Administrative File under Immunizations, marked as "FluMist Special Initiative 2008-09"
2 YEARS THROUGH 8 YEARS (without state insurance and for those with Medicaid and all others)	IMM-1	<ul style="list-style-type: none"> • Data enter into INC within 5 days • No forms/copies to be submitted to the Immunization Section
9 YEARS THROUGH 49 YEARS (includes Medicaid and all others)	IMM-FluMist Form	<ul style="list-style-type: none"> • Submit weekly all original IMM-FluMist forms to the Immunization Section • IMM-FluMist forms will be returned to the LHU by the Immunization Section after data entry • After receipt from Immunization Section retain in LHU Administrative File under Immunizations, marked as "FluMist Special Initiative 2008-09"

FINAL DISPOSITION

1. LHU will retain the original IMM-FluMist forms on all patients **including forms on children ages 6 months through 8 years with the designated state insurance.**
2. IMM-FluMist Form originals and copies will be retained in the LHU for 25 years.
3. Copies of the IMM-FluMist Forms for children 6 months through 8 years with the designated state insurance that are received by the Immunization Section will be destroyed.

FORMS:

See attached forms to be used in the special clinics administering FluMist.

1. IMM-FluMist, Revised 12/08
2. 2008-09 Influenza Vaccine Documentation
3. LAIV VIS, English
4. LAIV VIS, Spanish
5. Screening Questionnaire for Intranasal Influenza Vaccination, English
6. Screening Questionnaire for Intranasal Influenza Vaccination, Spanish

DISPOSAL OF UNUSED/EXPIRED VACCINE

At this time we are waiting on recommendations regarding disposal of unused vaccine. We will send out directions when they become available to us.