

IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE ATTENUATED INFLUENZA VACCINE (LAIV)

FLUMIST[®]

2006–2007 season update based on ACIP recommendations issued July 28, 2006:

- Healthy children ≥ 5 but < 9 years of age who have not previously received one dose of any influenza vaccine should be given a second dose ≥ 6 weeks after the initial dose, before the onset of influenza season if possible.
- Healthy household contacts and out-of-home caregivers of children < 60 months of age should receive an influenza vaccination.

I. ORDER:

1. Screen for contraindications.
2. Provide the current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. While the recipient is in an upright position, spray approximately 0.25mL from the LAIV sprayer intranasally into one nostril.
 - a. Pinch and remove the dose-divider clip from the plunger.
 - b. Place the tip just inside the other nostril and depress the plunger to deliver the remaining 0.25ml dose. (Total dose of 0.5 ml).
 - c. **For nasal use only. Do not administer parenterally.** This live vaccine can be administered simultaneously with other inactivated and live vaccines. However, two live vaccines not administered on the same day should be administered ≥ 4 weeks apart.

Pharmacist signature

Date

II. Licensed Live Attenuated Influenza Vaccine (Types A and B) 2006-2007			
Product Name	Vaccine Components	Acceptable Age Range	Thimerosal
FluMist ^{® 1} (MedImmune)	A/Wisconsin 67/2005 (H3N2) _ like A/New Caledonia/20/99 (H1N1) – like B/Malaysia/2506/2004 _ like antigens	5–49 years	NONE
¹ A live, trivalent, intranasally administered vaccine that replicates in the mucosa of the nasopharynx, inducing protective immunity against viruses included in the vaccine.			

III. VACCINE SCHEDULE FOR LAIV:

Age Group	Dosage Schedule ¹
Healthy adolescents and adults 15 through 49 years	1 dose (0.5ml) per season ²
¹ If the vaccine recipient sneezes after administration, the dose should not be repeated. ² One dose equals 0.5 ml, divided equally between each nostril.	

IV. RECOMMENDATIONS FOR USE

A. Vaccination with LAIV is indicated for healthy, non-pregnant persons 5–49 years of age in the following groups:

- **Household contacts and caregivers** of persons in any of the following high risk groups:
 - children <5 years of age
 - pregnant women
 - persons ≥ 50 years of age
 - children and adolescents who are receiving long-term aspirin therapy and, therefore, might be at risk for Reye syndrome;
 - persons with chronic disorders of the pulmonary or cardiovascular systems, including asthma;
 - persons with chronic metabolic diseases such as diabetes, renal dysfunction, or hemoglobinopathies;
 - persons with any condition that can compromise respiratory function or the handling or respiratory secretions or that can increase the risk for aspiration;
 - Residents of nursing homes and other chronic-care facilities; or
 - immunosuppressed persons other than those requiring a protected environment (e.g., hematopoietic stem-cell transplant recipients)
- Health-care workers
- Others who wish to reduce their risk of influenza

B. Persons who SHOULD NOT RECEIVE LAIV

- Persons <5 years of age or ≥ 50 years of age;*
- Persons with asthma, reactive airway disease, chronic disorders of the pulmonary or cardiovascular systems; metabolic diseases such as diabetes, renal dysfunction and hemoglobinopathies;*
- Persons with known or suspected immunodeficiency diseases or receiving immunosuppressive therapies (e.g. HIV, malignancy, leukemia, lymphoma, aglobulinemia, and thymic abnormalities);*
- Children or adolescents receiving aspirin or salicylates (because of the association of Reye syndrome with wild-type influenza virus infection);
- Persons with a history of Guillain–Barré Syndrome;**
- Pregnant women*;
- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs; or
- Household members and HCWs who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) requiring care in a protected environment.*

* These persons should receive inactivated influenza vaccine.

** These persons could receive inactivated influenza vaccine if their health care provider recommended that the benefits outweigh the risks.

V. VACCINE STORAGE AND HANDLING

- LAIV must be stored at -15°C (5°F) or below.¹
- LAIV must be thawed prior to administration by either:
 - Holding the sprayer in the palm of the hand and supporting the plunger rod with the thumb for 1 to 3 minutes (do not roll sprayer or depress plunger), OR
 - Thawing in a refrigerator and storing at 2-8°C (36-46°F) for ≤ 60 hours before use.²
- The vaccine should be administered immediately after thawing. If refrigerated vaccine is not used within 60 hours² of thawing it must be discarded.²
- Do not refreeze after thawing.
- Because this vaccine is so temperature-sensitive, it is not advisable to take it off site away from freezer or refrigeration.

¹ LAIV may now be stored in frost-free freezers without using freezer box.

² CDC. MMWR 2005; 54(RR-8): 18-9.

NOTE: For information regarding product storage and stability under conditions other than those stated above, contact MedImmune Vaccines Inc. or online at <http://www.FluMist.com>

VI. CONTRAINDICATIONS:

- A. Individuals with a history of Guillain- Barré syndrome.
- B. Persons with a history of severe (anaphylactic) allergy to egg or other LAIV vaccine components.

VII. PRECAUTIONS

- A. Administration of LAIV should be postponed until after the acute phase of a severe or moderate illness.
- B. Caution should be exercised if LAIV is administered to nursing mothers, since it is not known whether this vaccine is excreted in human milk.
- C. If clinical judgment indicates that nasal congestion might impede vaccine delivery to nasopharyngeal mucosa, deferral of administration should be considered until illness resolved.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS:

Common Side Effects in Adults

Runny nose/nasal congestion
Headache
Sore throat

Frequency

28%-78%
16%-44%
15-27%

Serious adverse events among healthy adults age 15_49 years occurred at a rate of < 1 %.

Adapted from reference in MMWR Vo. 52, (RR-13), 9/26/03, pg. 6.

IX. OTHER CONSIDERATIONS

Efficacy: 85% efficacious among 15 – 49 year olds.

A. Use with Influenza Antiviral Medications

Since the concurrent use of LAIV with antiviral compounds that are active against influenza A and B has not been evaluated, it is not advisable to administer LAIV until 48 hours after the cessation of antiviral therapy. Furthermore, antiviral agents should not be administered until two weeks after receipt of LAIV.

B. Shedding Vaccine virus

Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks post immunization.

C. Administering LAIV

Severely immunosuppressed persons should not administer LAIV. However, other persons at high risk for influenza complications may administer LAIV. These include persons with underlying medical conditions placing them at high risk, including pregnant women, persons with asthma, and persons aged ≥ 50 years.

D. Health-care workers or hospital visitors who have received LAIV should refrain from contact with severely immunosuppressed patients for 7 days after receipt of vaccine.¹

E. Timing of LAIV Administration

Administration of LAIV is not subject to tiered timing recommendations because it is not approved for use among populations at high risk. The optimal time to vaccinate is in October and November, but providers can begin vaccinating with LAIV as soon as vaccine supplies are available.

X. ADVERSE EVENTS REPORTING:

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510.

XI. REFERENCES:

1. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 9th ed. Washington, DC: Public Health Foundation, 2006: 233-53. Available at <http://www.cdc.gov/nip/publications/pink/flu.pdf>.
2. Prevention and Control of Influenza, MMWR 2006; 55 (RR-10), Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm>.
3. Using live, Attenuated Influenza Vaccine for Preventive Control of Influenza, MMWR 2003; 52 (RR13). Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5213.pdf>.
4. MedImmune Vaccines, Inc. 2006-2007 FluMist® package insert. Available at: <http://www.flumist.com/pdf/prescribinginfo.pdf>.

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, a consulting physician, or contact Oregon State Public Health Division Immunization Program at (971) 673-0300.

Electronic copy of this protocol available at:
<http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml>.
To request this material in an alternate format (e.g., Braille),
Please call (971) 673-0300.