

# Influenza Vaccine Intranasal

## (Seasonal) (Systemic)

Live, attenuated virus vaccine. Seasonal influenza virus vaccine live intranasal is a trivalent vaccine containing live (cold-adapted) influenza virus types A and B and is used to stimulate active immunity to influenza virus strains contained in the vaccine.

**Class:** Vaccines 80:12 (AHFS primary); im100 (VA primary)

**Brands:** FluMist®

## Uses

### Prevention of Seasonal Influenza A and B Virus Infections

- Prevention of seasonal influenza virus infection in adults 18–49 years of age, adolescents, and children  $\geq 2$  years of age.
- Influenza is an acute viral infection; influenza viruses spread from person to person mainly through large-particle respiratory droplet transmission. In the US, epidemics of seasonal influenza occur annually, usually during late fall through early spring. Influenza viruses can cause illness in any age group; children have highest rate of infection. Influenza can exacerbate underlying medical conditions or lead to pneumonia in certain individuals. Individuals  $\geq 65$  years of age, children  $< 2$  years of age, and individuals with chronic medical conditions have highest risk of influenza-related complications.
- Annual vaccination is the most effective strategy for preventing seasonal influenza and its complications. Immunization efforts focus on vaccinating individuals at risk for influenza complications and contacts of these individuals.
- For prevention of seasonal influenza infection, 2 different types of influenza vaccine are commercially available in the US: intranasal vaccine containing live, attenuated virus and parenteral vaccine containing inactivated virus subunits. Both vaccine types contain influenza virus strains antigenically equivalent to the annually recommended seasonal influenza strains and are considered effective in children and adults; however, data directly comparing the efficacy of these 2 types of seasonal influenza vaccines are limited. Possible advantages of the intranasal live vaccine include its potential to induce a broad mucosal and systemic immune response, ease of administration, and improved acceptance of intranasal rather than IM administration; possible disadvantages include restrictions based on age or medical conditions and risk that the live vaccine virus could be transmitted from the vaccinee to close contacts who are severely immunocompromised. (See Transmission of Vaccine Virus under Cautions.)
- USPHS Advisory Committee on Immunization Practices (ACIP), AAP, American Academy of Family Physicians (AAFP), and other experts state that seasonal intranasal live influenza vaccine can be used instead of seasonal parenteral inactivated vaccine for prevention of seasonal influenza infection in nonpregnant adults and children 2–49 years of age who do not have underlying medical conditions that put them at higher risk for influenza complications. This includes health-care personnel, household contacts, and other individuals (e.g., day-care providers) who are in close contact with individuals at high risk of influenza complications or in close contact with certain immunocompromised individuals (e.g., those not requiring a protective environment, those with diabetes or HIV infection, asthma patients taking corticosteroids).
- Do *not* use seasonal intranasal live influenza vaccine in health-care workers, household members, or other individuals who have close contact with severely immunocompromised individuals requiring a protective environment (e.g., hematopoietic stem cell transplant [HSCT] recipients). (See Individuals with Altered Immunocompetence and Their Close Contacts under Cautions.) Use the seasonal parenteral inactivated influenza vaccine in these individuals.
- Travelers who want to reduce their risk for influenza infection should receive vaccination with seasonal influenza vaccine, preferably at least 2 weeks before departure. The risk for exposure to seasonal influenza during travel depends on the time of year and destination. In the tropics, influenza can occur throughout the year; in temperate regions of the southern hemisphere, influenza activity generally occurs from April through September; in temperate climates, travelers also may be exposed to influenza during the summer (especially when traveling as part of large tourist groups that include individuals from areas of the world where influenza is circulating). ACIP recommends that travelers (especially those at high risk for influenza complications) be vaccinated against seasonal influenza before travel if they were not vaccinated during the preceding fall or winter, will be traveling to the tropics, traveling with organized tourist groups at any time of year, or traveling to the southern hemisphere between April and September.
- Safety and efficacy of intranasal live influenza vaccine *not* established in children  $< 2$  years of age or adults  $\geq 50$  years of age; use the parenteral inactivated seasonal influenza vaccine in these age groups.

- Safety of intranasal live influenza vaccine *not* established in individuals with underlying medical conditions that may predispose them to severe disease following influenza infection; use the seasonal parenteral inactivated influenza vaccine in these individuals.
- Influenza vaccines are *not* effective against all strains of influenza, but may be effective against those strains (and closely related strains) represented in the vaccine.
- Seasonal influenza vaccines for the 2009–2010 influenza season are *not* expected to provide protection against infection with the 2009 pandemic influenza A (H1N1) virus, previously referred to as the novel 2009 influenza A (H1N1) virus or swine-origin influenza A (H1N1) virus. Influenza A (H1N1) 2009 monovalent vaccine may be indicated in certain groups at highest risk for infection or influenza-related complications to prevent infection caused by this strain. Seasonal influenza vaccines also are *not* expected to provide protection against infection with avian influenza A viruses, including avian influenza A (H5N1).
- Information regarding influenza surveillance and updated recommendations for prevention and treatment of seasonal influenza is available from CDC at <http://www.cdc.gov/flu>. CDC information regarding prevention and treatment of 2009 influenza A (H1N1) is available from CDC at <http://www.cdc.gov/h1n1flu> and information regarding avian influenza A (H5N1) is available at <http://www.cdc.gov/flu/avian>.

## Dosage and Administration

### Administration

#### Intranasal Administration

Administer intranasally using the prefilled, single-use sprayer supplied by the manufacturer.

Do *not* administer IM, IV, or intradermally.

Intranasal live influenza vaccine is a colorless to pale yellow liquid and may be clear to slightly cloudy. Do *not* mix with any other vaccine or solution.

Administer every year before exposure to seasonal influenza. Optimum time for annual vaccination against seasonal influenza cannot be determined since influenza seasons vary in timing and duration and more than one outbreak might occur in a single community in a single year. In the US, localized outbreaks indicating start of the annual influenza season can occur as early as October; peak influenza activity often occurs in January or February, but has occurred as late as April or May. Begin vaccination efforts each year as soon as the seasonal influenza vaccine is available (usually available beginning in September or October); continue vaccination efforts throughout influenza season.

When planning influenza vaccination efforts for the 2009–2010 influenza season, consider that vaccination against the 2009 pandemic influenza A (H1N1) virus, previously referred to as the novel 2009 influenza A (H1N1) virus or swine-origin influenza A (H1N1) virus, may be indicated in addition to vaccination against seasonal influenza in certain individuals and may create additional burden on vaccination programs and health-care providers. To reduce potential overlap between vaccination against seasonal influenza and vaccination against the 2009 influenza A (H1N1) virus, ACIP recommends that immunization against seasonal influenza be initiated as soon as the seasonal vaccine is available (e.g., September).

Intranasal live influenza vaccine must be administered by a health-care provider. Severely immunosuppressed individuals should *not* administer the vaccine. (See Administration Precautions under Cautions.) Other individuals at high-risk of influenza complications (e.g., those with underlying medical conditions, pregnant women, individuals with asthma, individuals  $> 50$  years of age) may administer the vaccine.

Place recipient in an upright position with head tilted back. Administer approximately one-half the contents of the prefilled, single-use sprayer into each nostril. Consult manufacturer's labeling for specific information regarding use of the sprayer.

After administering vaccine, carefully dispose of the sprayer (i.e., discard using standard procedures for medical waste).

If vaccine recipient sneezes after receiving a dose, do *not* repeat the dose.

If nasal congestion will impede delivery of vaccine to nasopharyngeal mucosa, defer administration until symptoms subside. Alternatively, use the parenteral inactivated seasonal influenza vaccine.

May be given simultaneously with other age-appropriate vaccines during same health-care visit. However, ACIP states that simultaneous administration of seasonal intranasal live influenza vaccine and intranasal live influenza A 2009 (H1N1) monovalent vaccine is *not* recommended. (See Interactions.)

### Dosage

Dosing schedule for prevention of seasonal influenza depends on individual's age and vaccination status.

A single-dose regimen is used in adults and children  $\geq 9$  years of age. To promote an adequate antibody response, a 2-dose regimen is used in children 2–8 years of age who have not previously received influenza vaccine.

A single dose consists of the entire contents of the sprayer (0.2 mL).

#### Pediatric Patients

### Prevention of Seasonal Influenza A and B Virus Infections >Children 2–8 Years of Age

**Intranasal:** Have not previously received any type of seasonal influenza vaccine: 2 doses administered at least 1 month apart. Each dose consists of 0.2 mL (0.1 mL in each nostril).  
Previously received 2 doses of any type of seasonal influenza vaccine during a single influenza season: Single dose consisting of 0.2 mL (0.1 mL in each nostril).  
Received any type of seasonal influenza vaccine for the first time during a previous season and did not receive a second dose during the same season: ACIP and AAP recommend 2 doses the following season given at least 1 month apart. Each dose consists of 0.2 mL (0.1 mL in each nostril).

**>Children and Adolescents 9–17 Years of Age**

**Intranasal:** Single dose consisting of 0.2 mL (0.1 mL in each nostril).

**Adults**

**Prevention of Seasonal Influenza A and B Virus Infections**

**>Adults 18–49 Years of Age**

**Intranasal:** Single dose consisting of 0.2 mL (0.1 mL in each nostril).

**Special Populations**

**Hepatic Impairment**

No specific dosage recommendations.

**Renal Impairment**

No specific dosage recommendations.

**Geriatric Patients**

Not indicated in adults ≥50 years of age, including geriatric adults.

## Cautions

**Contraindications**

- History of hypersensitivity (especially anaphylactic reactions) to egg or egg proteins, gentamicin, gelatin, or arginine.
- Life-threatening reaction to previous dose of influenza vaccine.
- Children and adolescents 2–17 years of age receiving aspirin or aspirin-containing therapy because of association of Reye's syndrome with aspirin use and wild-type influenza infection.

**Warnings/Precautions**

**Sensitivity Reactions**

**Hypersensitivity Reactions**

Hypersensitivity reactions (e.g., anaphylactic reaction, facial edema, urticaria) reported.

Seasonal intranasal live influenza vaccine is produced using eggs and can contain residual egg protein that may induce immediate hypersensitivity reactions, including anaphylaxis, in individuals with severe egg allergy. ACIP states asking patients if they can eat eggs without adverse effects is a reasonable way to identify those who may be at risk for allergic reactions if they receive the vaccine. Those who can eat safely eggs or egg products usually can receive the vaccine; those with a history of anaphylactic or other immediate hypersensitivity reaction (e.g., hives, angioedema, allergic asthma) to eggs or egg proteins should *not* receive the vaccine. (See Contraindications under Cautions.)

Appropriate medical treatment and supervision must be readily available in case anaphylaxis occurs.

Do *not* administer additional vaccine doses to any individual who had a life-threatening reaction to a previous dose. (See Contraindications under Cautions.)

**Infants <24 Months of Age**

Do *not* use in infants <24 months of age; increased risk of wheezing and hospitalization reported in clinical trials in this age group. (See Pediatric Use under Cautions.)

**Individuals with Asthma or Recurrent Wheezing**

Do *not* use in individuals with asthma or in children <5 years of age with history of recurrent wheezing or a recent wheezing episode (during the past 12 months) unless potential benefits outweigh risks; increased risk of wheezing in such individuals. (See Pediatric Use under Cautions.)

Do *not* use in individuals with severe asthma or active wheezing; not evaluated to date in such individuals.

**Guillain-Barré Syndrome**

Carefully consider possible benefits and potential risks of intranasal live influenza vaccine in individuals who experienced Guillain-Barré syndrome (GBS) within 6 weeks of previous influenza vaccination.

Unclear whether influenza vaccination increases risk of recurrence of GBS. AAP states that influenza vaccines should not be used in children who developed GBS within 6 weeks after a previous dose of any influenza vaccine. ACIP states that, as a precaution, individuals who are not at high risk for severe influenza complications and who developed GBS within 6 weeks of a previous dose of influenza vaccine generally should avoid influenza vaccination. Although data are limited, ACIP states that use of influenza vaccine can be considered in individuals with a history of GBS who are at high risk for severe complications from influenza.

**Individuals with Altered Immunocompetence and Their Close Contacts**

Only limited data available regarding safety and efficacy in immunocompromised individuals. Carefully consider possible benefits and potential risks in such individuals.

ACIP states live viral vaccines (including intranasal live influenza vaccine) usually should not be used in immunocompromised individuals, except in certain circumstances. These experts state use of live virus vaccines can be considered in patients with leukemia, lymphoma, or other malignancies if the disease is in remission and chemotherapy was terminated at least 3 months prior to vaccination. (See Specific Drugs under Interactions.)

Has been used in a limited number of HIV-infected adults (asymptomatic or mildly symptomatic) in a clinical study; no serious adverse effects reported, but efficacy not evaluated. CDC, National Institutes of Health (NIH), IDSA, AAP, and other experts state that HIV-infected children, adolescents, and adults should receive annual vaccination against seasonal influenza; however, the parenteral inactivated influenza vaccine (not the intranasal live vaccine) should be used for prevention of seasonal influenza in HIV-infected individuals.

Because of possible transmission of live vaccine viruses, intranasal live influenza vaccine should *not* be administered to close contacts of severely immunocompromised individuals requiring a protective environment (e.g., HSCT recipients); however, ACIP states that the vaccine may be administered to close contacts of less severely immunocompromised individuals (e.g., those not requiring a protective environment).

In addition, because of possible transmission of live vaccine viruses, ACIP states that health-care workers who have received the intranasal vaccine should avoid contact with severely immunocompromised patients requiring a protective environment (e.g., HSCT recipients) for 7 days after vaccination. Hospital visitors who have received the vaccine should avoid contact with severely immunosuppressed patients for 7 days after vaccination but may visit patients who are not severely immunosuppressed.

**Individuals with Medical Conditions that Increase Risk of Influenza Complications**

Safety *not* established in individuals with underlying medical conditions that increase risk for complications following wild-type influenza infection (e.g., asthma, reactive airway disease, chronic pulmonary or cardiovascular disorders, diabetes, renal impairment, hemoglobinopathies, known or suspected immunodeficiency). (See Individuals with Altered Immunocompetence and Their Close Contacts under Cautions.) Do not use in these individuals unless possible benefits outweigh risks.

**Transmission of Vaccine Virus**

Intranasal influenza vaccine contains live, attenuated virus. Vaccine virus capable of infection and replication is present in nasal secretions of vaccine recipients and viral shedding occurs in adults and children who have received the intranasal live vaccine.

Relationship between vaccine virus replication in vaccine recipients and transmission of vaccine virus to other individuals not established. However, transmission of vaccine virus has occurred rarely between vaccine recipients and their contacts.

Duration of vaccine virus replication and shedding in vaccine recipients not established.

**Limitations of Vaccine Effectiveness**

May require up to 2 weeks for protection to develop following seasonal influenza vaccination.

May not protect all vaccine recipients against influenza.

Seasonal influenza vaccine is formulated annually to contain influenza A and B antigens predicted to represent strains of influenza virus likely to circulate in the US during the upcoming influenza season. (See Actions.) Efficacy of the seasonal vaccine during any given year depends on how closely viral strains represented in the vaccine match viral strains circulating during the season.

Intranasal influenza vaccine for the 2009–2010 influenza season is *not* expected to provide protection against the 2009 pandemic influenza A (H1N1) virus, previously referred to as the novel 2009 influenza A (H1N1) virus or swine-origin influenza A (H1N1) virus, and is *not* expected to provide protection against infection with avian influenza A viruses, including avian influenza A (H5N1).

**Duration of Immunity**

Immunity declines during the year after seasonal influenza vaccination. In addition, circulating strains of seasonal influenza virus change from year to year. Annual vaccination is needed for prevention of seasonal influenza.

Do *not* administer vaccine from a previous influenza season in an attempt to provide protection during a subsequent influenza season.

**Concomitant Illness**

ACIP states that minor acute illness, such as mild diarrhea or mild upper respiratory tract infection (with or without fever), generally does not preclude vaccination. If nasal congestion will impede delivery of the vaccine to the nasopharyngeal mucosa, defer administration until illness resolves.

**Administration Precautions**

Health-care personnel who are severely immunosuppressed should *not* administer intranasal live influenza vaccine to patients. Small amounts of vaccine virus are likely to be introduced into the environment; the risk of acquiring vaccine virus from the environment is unknown, but presumed to be limited.

**Improper Storage and Handling**

Improper storage or handling of vaccines may result in loss of vaccine potency and reduced immune response in vaccinees.

Inspect all vaccines upon delivery and monitor during storage to ensure that the appropriate temperature is maintained.

Do *not* administer vaccine that has been mishandled or has not been stored at the recommended temperature. (See Storage under Stability.) If there are concerns about mishandling, contact the manufacturer or state or local health departments for guidance on whether the vaccine is usable.

### Specific Populations

#### Pregnancy

Category C.

Manufacturer states that the vaccine should be used in pregnant women only when clearly needed.

ACIP, American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), NIH, IDSA, and other experts state that parenteral inactivated influenza vaccine (not intranasal live influenza vaccine) should be used for prevention of seasonal influenza in pregnant women.

#### Lactation

Not known whether influenza virus live is distributed into milk. Manufacturer recommends caution.

ACIP states that either seasonal intranasal live influenza vaccine or seasonal parenteral inactivated influenza vaccine can be used for prevention of seasonal influenza in nursing women, unless contraindicated.

#### Pediatric Use

Safety and efficacy established only in children  $\geq 2$  years of age.

*Not* indicated in infants <24 months of age. Increased incidence of wheezing and hospitalization reported in a clinical trial in infants 6–23 months of age† who received intranasal live influenza vaccine compared with those who received parenteral inactivated seasonal influenza vaccine.

Do *not* use in children with asthma or in children <5 years of age with a history of recurrent wheezing or a recent wheezing episode.

When considering use in children 2 through 4 years of age, ACIP and AAP recommend that clinicians screen for possible reactive airways diseases by consulting the child's medical record and asking the child's parent or guardian if wheezing or asthma episodes were identified by a health-care provider within the past 12 months. The seasonal parenteral inactivated influenza vaccine should be used instead of the intranasal live vaccine for prevention of seasonal influenza in such children.

Protection of young infants against seasonal influenza virus depends on immunization of their close contacts. All household contacts, health-care and day-care providers, and other close contacts of young infants should receive seasonal influenza vaccination appropriate for their age and target group.

#### Adults 50–64 Years of Age

*Not* indicated for use in adults 50–64 years of age. Efficacy *not* demonstrated in adults 50–64 years of age. Use seasonal parenteral inactivated influenza vaccine for prevention of seasonal influenza in this age group.

#### Geriatric Use

*Not* indicated for use in geriatric individuals  $\geq 65$  years of age. Use seasonal parenteral inactivated influenza vaccine for prevention of seasonal influenza in geriatric adults.

### Common Adverse Effects

Children 2–6 years of age: Runny nose/nasal congestion, decreased appetite, irritability, lethargy, sore throat, fever, headache, muscle aches, chills.

Older children and adolescents up to 17 years of age: Adverse effects similar to those reported in younger children; in addition, abdominal pain and decreased activity.

Adults 18–49 years of age: Runny nose, headache, sore throat, tiredness/weakness, muscle aches, cough, chills, nasal congestion, sinusitis.

## Drug Interactions

### Inactivated Vaccines and Toxoids

Safety and immunogenicity of intranasal live influenza vaccine administered concomitantly with age-appropriate inactivated vaccines not determined. Manufacturer states risks versus benefits of concomitant administration of the intranasal live influenza vaccine and inactivated vaccines should be considered.

ACIP and AAP state that, in the absence of specific data indicating interference, inactivated vaccines or toxoids can be administered simultaneously with or at any interval before or after seasonal intranasal live influenza vaccine.

### Live Vaccines

Intranasal influenza vaccine is a live, attenuated virus vaccine. ACIP and AAP state that influenza virus vaccine live intranasal and other live vaccines generally may be administered simultaneously on the same day. However, ACIP states that simultaneous administration of seasonal intranasal live influenza vaccine and intranasal live influenza A (H1N1) monovalent vaccine is *not* recommended.

ACIP states that some oral live vaccines (e.g., rotavirus vaccine live oral, typhoid vaccine live oral) can be administered concomitantly with or at any interval before or after intranasal live influenza vaccine. However, because of theoretical concerns that the immune response to other live virus vaccines might be impaired if given within 30 days of another live virus vaccine, ACIP and AAP state that if intranasal live influenza vaccine and other live vaccines are not administered

on the same day, they should be administered at least 4 weeks apart. (See Specific Drugs under Interactions.)

### Specific Drugs

Drug	Interaction	Comments
<b>Antiviral agents active against influenza (amantadine, rimantadine, oseltamivir, zanamivir)</b>	Concomitant use of intranasal live influenza vaccine and antivirals used for treatment or prevention of influenza not studied; these antivirals potentially could decrease response to the live vaccine	Do not administer intranasal live influenza vaccine until at least 48 hours after influenza antiviral agent discontinued; do not administer influenza antiviral agent until at least 2 weeks after the vaccine, unless medically necessary  If influenza antiviral agent and intranasal live influenza vaccine are administered concomitantly, consider revaccination if appropriate; ACIP recommends revaccination if an influenza antiviral was given 2 days before to 14 days after vaccination
<b>Aspirin</b>	Association of Reye's syndrome with aspirin and wild-type influenza infection	Contraindicated in children and adolescents receiving aspirin or aspirin-containing therapy
<b>Blood products</b>		May be administered simultaneously with or at any time before or after whole blood, packed red blood cells, plasma, and platelet products without substantially decreasing antibody response to the vaccine
<b>Immune globulin (immune globulin IM [IGIM], immune globulin IV [IGIV]) or specific immune globulin (hepatitis B immune globulin [HBIG], rabies immune globulin [RIG], tetanus immune globulin [TIG], varicella zoster immune globulin [VZIG])</b>	No evidence that immune globulin preparations interfere with immune response to intranasal live influenza vaccine	Intranasal live influenza vaccine may be given simultaneously with or at any interval before or after immune globulin preparations
<b>Immunosuppressive agents (e.g., alkylating agents, antimetabolites, corticosteroids, radiation)</b>	Potential for decreased antibody response to intranasal live influenza vaccine and increased risk of adverse reactions	Should not be used in those receiving immunosuppressive therapy  Optimum interval between discontinuance of immunosuppressive therapy and subsequent administration of a live viral vaccine has not been determined  Live viral vaccines generally should not be administered for at least 3 months after immunosuppressive therapy is discontinued, including chemotherapy or radiation for

		leukemia, other hematopoietic malignancies, or solid tumors, or after solid organ transplant
		Systemic corticosteroid therapy (prednisone or equivalent) in a dosage $\geq 2$ mg/kg daily or $\geq 2$ mg daily given for $\geq 2$ weeks is considered immunosuppressive; delay administration of live vaccines for at least 1 month after such therapy is discontinued
		Corticosteroid therapy involving short-term (<2 weeks), low- to moderate-dose systemic therapy (<20 mg prednisone or equivalent daily); long-term, alternate-day systemic therapy using short-acting drugs; maintenance physiologic doses (replacement therapy); topical therapy (e.g., cutaneous, ophthalmic); inhalation; or intra-articular, bursal, or tendon injections should not be immunosuppressive and does not usually contraindicate use of live vaccines
<b>Influenza A (H1N1) 2009 monovalent vaccine</b>		Intranasal live influenza A (H1N1) monovalent vaccine: Data not available regarding concomitant administration with seasonal intranasal live influenza vaccine; ACIP states simultaneous administration <i>not</i> recommended
<b>Intranasal preparations</b>	Concomitant administration not evaluated	
<b>Measles, mumps, and rubella vaccine (MMR)</b>	Simultaneous administration of intranasal live influenza vaccine with MMR and monovalent varicella vaccine in infants 12–15 months of age did not interfere with the immune response to any of the antigens and did not increase frequency of adverse effects; safety and immunogenicity of simultaneous administration not evaluated in infants >15 months of age	If not given simultaneously, give at least 4 weeks apart whenever possible
<b>Rotavirus vaccine (RV)</b>	No evidence to date of reduced antibody responses if oral rotavirus vaccine is administered concomitantly with	May be administered concomitantly with or at any interval before or after intranasal live influenza vaccine

		intranasal live influenza vaccine
<b>Varicella vaccine (VAR)</b>	Simultaneous administration of intranasal live influenza vaccine with monovalent varicella vaccine and MMR vaccine in infants 12–15 months of age did not interfere with the immune response to any of the antigens and did not increase frequency of adverse effects; safety and immunogenicity of concomitant administration not evaluated in infants >15 months of age	If not given simultaneously, give at least 4 weeks apart whenever possible

## Stability

### Storage

**Intranasal Spray**  
**Solution**

2–8°C; do not freeze.  
Does not contain thimerosal or any other preservatives.

## Actions

- Influenza virus vaccine live intranasal that is used for prevention of seasonal influenza is a trivalent vaccine containing live, attenuated (cold-adapted) influenza virus types A and B.
- Seasonal influenza vaccines are formulated annually to contain influenza A (H3N2), influenza A (H1N1), and influenza B viruses likely to circulate in the US during the next influenza season.
- The seasonal 2009–2010 intranasal live influenza vaccine for the US contains A/South Dakota/6/2007 (H1N1) (*A/Brisbane/59/2007-like*), A/Uruguay/716/2007 (H3N2) (*A/Brisbane/10/2007-like*), and B/Brisbane/60/2008.
- Only 1 of 3 antigens contained in the seasonal 2009–2010 influenza vaccine (the influenza type B component) differs from the antigens contained in the vaccine used during the previous influenza season (2008–2009).
- Seasonal intranasal live influenza vaccine is antigenically equivalent to seasonal parenteral inactivated influenza vaccine.
- Influenza vaccines stimulate active immunity to influenza virus strains represented in the vaccines.
- Following administration of intranasal live influenza vaccine, vaccine virus replicates in cells lining the nasopharynx. Protective mechanism not completely understood; may involve both serum and mucosal antibodies.
- Efficacy of seasonal influenza vaccine in preventing seasonal influenza virus infection depends on whether the virus strains represented in the vaccine are antigenically similar to influenza virus strains circulating during the influenza season.
- Seasonal influenza vaccines for the 2009–2010 influenza season are *not* expected to provide protection against the 2009 pandemic influenza A (H1N1) virus, previously referred to as the novel 2009 influenza A (H1N1) or swine-origin influenza A (H1N1) virus, and are *not* expected to provide protection against infection with avian influenza A viruses, including avian influenza A (H5N1).

## Advice to Patients

- Prior to administration of seasonal influenza virus vaccine live, provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient or patient's legal representative (VISs are available at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>).
- Advise patient and/or patient's parent or guardian of the risks and benefits of vaccine administration.
- Importance of annual vaccination against seasonal influenza.
- Advise patient and/or patient's parent or guardian that a single dose of seasonal influenza vaccine is necessary each year in adults, adolescents, and children  $\geq 9$  years of age, but that 2 doses are necessary in children 2–8 years of age who have not previously received 2 doses of any seasonal influenza vaccine during a single influenza season.
- Ask patient and/or patient's parent or guardian if vaccinee has a history of asthma or recurrent wheezing or has had a recent wheezing episode (within the past 12 months). Advise patient's parent or guardian that a history of recurrent wheezing may be an asthma equivalent in children <5 years of age. (See Pediatric Use under Cautions.)

- Advise patient and/or patient's parent or guardian that seasonal intranasal influenza vaccine is a live, attenuated virus vaccine and that vaccine virus can be transmitted to close contacts. Necessity of vaccine recipient avoiding close contact with severely immunocompromised individuals for 7 days following vaccination. (See Individuals with Altered Immunocompetence and Their Close Contacts under Cautions.)
- Importance of informing clinicians of adverse effects. Clinicians or individuals can report any adverse reactions that occur following vaccination to the manufacturer at 877-633-4411 or Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or <http://www.vaers.hhs.gov/>.
- Importance of informing clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs, as well as concomitant medical problems (i.e., asthma, recurrent wheezing, GBS).
- Importance of women informing clinician if they are or plan to become pregnant or plan to breast-feed.
- Importance of informing patients of other precautionary information. (See Cautions.)

## Preparations

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

### Influenza Virus Vaccine Live Intranasal Trivalent Types A and B (2009–2010)

#### Nasal Solution

106.5-7.5 FFU (fluorescent focus units) each of A/South Dakota/6/2007 (H1N1) (A/Brisbane/59/2007-like), A/Uruguay/716/2007 (H3N2) (A/Brisbane/10/2007-like), and B/Brisbane/60/2008 per 0.2 mL

**FluMist**<sup>®</sup> (preservative-free; available in 0.2-mL prefilled single-use sprayers), MedImmune