FDA Approves Nasal Spray Influenza Vaccine for Self or Caregiver Administration

FluMist is the first influenza vaccine does not need to be administered by a health care provider.

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[On September 20], the U.S. Food and Drug Administration approved FluMist for self- or caregiver administration. FluMist is approved for the prevention of influenza disease caused by influenza virus subtypes A and B in individuals 2 through 49 years of age.

FluMist is sprayed into the nose and has been used safely and effectively for many years. It was initially approved by the FDA in 2003 for use in individuals 5 through 49 years of age, and in 2007, the FDA approved the use of FluMist to include children 2 through 5 years of age. It is the first vaccine to prevent influenza, more commonly known as the flu, that does not need to be administered by a health care provider.

“Today’s approval of the first influenza vaccine for self- or caregiver administration provides a new option for receiving a safe and effective seasonal influenza vaccine potentially with greater convenience, flexibility and accessibility for individuals and families,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research. “Getting vaccinated each year is the best way to prevent influenza, which causes illness in a substantial proportion of the U.S. population every year and may result in serious complications, including hospitalization and death. This approval adds another option for vaccination against influenza disease and demonstrates the FDA’s commitment to advancing public health.”

The flu is a common and contagious respiratory disease that is caused by influenza viruses that typically circulate during the fall and winter in the U.S. It can cause mild to severe illness with a range of symptoms that usually appear suddenly, such as body aches, fever, coughing, sore throat, tiredness and a stuffy or runny nose. Flu can be life-threatening and cause serious complications that can lead to hospitalization or death, particularly in high-risk groups such as the elderly, young children and people with certain chronic medical conditions.

Each flu season is different and the health impacts can be substantial and vary widely from season to season, with some flu seasons being worse than others. According to the U.S. Centers for Disease Control and Prevention, flu has resulted in about 9.3 million to 41 million illnesses,

100,000 to 710,000 hospitalizations and 4,900 to 51,000 deaths annually between 2010 and 2023. Numerous FDA-approved vaccines are available each flu season to prevent influenza.

FluMist contains a weakened form of live influenza virus strains and is sprayed in the nose. A prescription is still required to receive FluMist. There are now two approved options for receiving FluMist. The vaccine may be administered by a health care provider in a health care setting (including a pharmacy) or it may be administered by the vaccine recipient or a caregiver who is 18 years of age or older.

The most commonly reported side effects of FluMist are fever over 100°F in children 2 through 6 years of age, runny nose and nasal congestion in individuals 2 through 49 years of age and a sore throat in adults 18 through 49 years of age.

For those interested in self- or caregiver administration, the vaccine manufacturer plans to make the vaccine available through a third-party online pharmacy. Those who choose this option will complete a screening and eligibility assessment when they order FluMist. The third-party pharmacy determines eligibility based on the completed screening and, if it is determined that the intended vaccine recipient is eligible, the pharmacy writes the prescription and ships the vaccine to the address provided by the individual who placed the order. The vaccine can then be administered to the prescribed household member(s) at their convenience. A caregiver should administer FluMist to individuals 2 through 17 years of age, as individuals in this age group should not self-administer the vaccine.

A study was conducted with vaccine recipients and caregivers to evaluate whether the instructions for use were appropriately designed so that recipients and caregivers could safely and effectively use the vaccine.

Vaccine recipients and caregivers who administer FluMist will be sent the vaccine, the Prescribing Information, Information for Patients and their Caregivers and Instructions for Use. The Instructions for Use provides detailed instructions for storage, administration and disposal of FluMist.

The FDA granted this approval of FluMist (Influenza Vaccine Live, Intranasal) to MedImmune LLC.

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