FluMist approved for self-administration in US

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Only influenza vaccine approved for self- or caregiver-administration at home, expanding options for influenza protection

FluMist has been approved in the US as the only self-administered influenza vaccine. *FluMist*, a needle-free nasal spray, was approved to be self-administered by adults up to 49 years of age or administered by a parent/caregiver to individuals 2-17 years of age.[1]

The approval by the US Food and Drug Administration (FDA) was based on a comprehensive submission, which included results from a usability study demonstrating that individuals over 18 years of age could self-administer or administer *FluMist* to eligible individuals 2-49 years of age.[1]

Ravi Jhaveri, MD, Division Head, Infectious Disease; Virginia H. Rogers Professor in Infectious Diseases, Professor of Pediatrics (Infectious Diseases), Northwestern University School of Medicine, Chicago, US, said: "For the first time, families and caregivers will be able to protect themselves against influenza with a needle-free, self-administered vaccine, from the convenience of their own home. Each year, influenza poses a significant burden for people, society and health systems; additional tools to increase access to vaccinations, while also reducing disparities, are critical."

Iskra Reic, Executive Vice President, Vaccines and Immune Therapies, AstraZeneca, said: "The approval of *FluMist* for self-administration is an important step forward in making vaccines more accessible to fight the high annual burden of influenza. For more than 20 years, *FluMist* has been the only nasal spray flu vaccine licensed in the US and now it is also the only vaccine to help individuals, families and communities access an influenza vaccine conveniently through self- and caregiver administration outside of traditional healthcare settings."

Seasonal influenza causes up to 1 billion infections each year and may result in severe outcomes for about 3-5 million patients including hospitalisations, complications and death.[2] Influenza has been shown to impact school attendance and employment with 47% of days of school and 1-2 days of work missed annually.[3,4] Vaccination rates for influenza have declined in adults in the US since the 2020-21 season by 3.3%.[5] In a US survey, a common reason for adults not to receive a vaccination included failure to attend regular well-care visits, while having access to at-home vaccination options were shown to potentially increase influenza vaccination uptake.[6]

Once available, individuals 18 and older will be able to have FluMist delivered directly to their homes via FluMist Home. FluMist Home will utilise an online pharmacy where eligible individuals complete a questionnaire that is reviewed by a pharmacist prior to receiving their vaccine for shipment. FluMist will continue to be available in offices and pharmacies for administration by healthcare professionals. More information is available at www.FluMist.com.

Notes

Influenza

On average, about 8% of the US population becomes ill from influenza each season, with a range of between 3 percent and 11 percent, depending on the season.[7] During the 2022-2023 influenza season, an estimated 31 million people developed illness from influenza, 14 million visited a healthcare provider for influenza, with 360,000 hospitalisations, and 21,000 deaths.[8]

About *FluMist* Live Attenuated Influenza Vaccine

FluMist is a live attenuated influenza vaccine (LAIV), which is administered as a nasal spray for the prevention of influenza. *FluMist* is an Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics (AAP) recommended influenza vaccine option. *FluMist* was originally approved in the US in 2003 and since then almost 200 million doses have been distributed around the world.[1]

Human Factors Usability Study for FluMist Self Administration

In FDA-required human factors/usability studies, AstraZeneca evaluated if individuals 18 through 49 years of age could appropriately administer *FluMist* when given instructions for use. The results showed that 100% of intended users administered a full dose. In addition, data show that efficacy, immunogenicity and adverse events with self-administration of *FluMist* are similar to that seen with HCP-administered vaccination.[1,9] The *FluMist* label has been updated to provide additional instructions for ordering and administration for eligible self and caregiver use. Children 2-8 years of age with an uncertain vaccination history may not be eligible for caregiver use and should consult their healthcare provider for further information.[1]

AstraZeneca

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Contacts

For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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