COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252-ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

FDA Approves FluMist Vaccine for Self-Administration

On September 20th, The Food and Drug Administration (FDA) approved the nasal influenza vaccine, FluMist, for self- or caregiver- administration, provided the recipeint or caregiver is 18 years of age or older. It is the first flu vaccine that does not need to be administered by a healthcare professional.

Background

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. The flu 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.

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 contains a weakened form of live influenza virus strains and is sprayed into the nose. It has been used safely and effectively for many years.

For the current 2024-2025 influenza season, FluMist is available for administration by a healthcare provider only. The manufacturer of FluMist (MedImmune, LLC) expects that FluMist will be available for the 2025-2026 influenza season for self or caregiver administration.

Data from Clinical Trials

The approval for self-adminsitration of FluMist is based on the results of a study that examined whether FluMist's instructions were clear enough to safely and effectively adminsiter the vaccine at home. The study was an open-label, randomized, controlled trial that was conducted from 2012 to 2014 and included a total of 1,077 subjects. Subjects were divided into two groups: 1) self-administration (SA) group and 2) healthcare worker-administered (HCWA) group. All subjects in the SA group administered FluMist correctly and, at follow-up, the majority (64%) preferred the SA vaccine over the HCWA vaccine. The most common adverse reactions were runny nose or nasal congestion (ages 2 years through 49 years), fever over 100°F (children ages 2 years through 6 years), and sore throat (adults ages 18 years through 49 years).

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REFERENCES:

1. Lutton, L. (2024, September 20). *FDA approves Flumist vaccine for self-administration.* Managed Healthcare Executive. https://www.managedhealthcareexecutive.com/view/fda-approves-flumist-vaccine-for-self-administration MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda\
2. U.S. Food and Drug Administration. (2024). *FluMist*. https://www.fda.gov/vaccines-blood-biologics/vaccines/flumist
3. Commissioner, O. of the. (2024, September 20). *FDA approves nasal spray influenza vaccine for self- or caregiver-administration*. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-nasal-spray-influenza-vaccine-self-or-caregiver-administration#:~:text=FDA%20approves%20FluMist%20for%20self-%20or%20caregiver-administration.
4. Burgess, T. H., Murray, C. K., Bavaro, M. F., Landrum, M. L., O'Bryan, T. A., Rosas, J. G., Cammarata, S. M., Martin, N. J., Ewing, D., Raviprakash, K., Mor, D., Zell, E. R., Wilkins, K. J., & Millar, E. V. (2015). *Self-administration of intranasal influenza vaccine: Immunogenicity and volunteer acceptance*. Vaccine, 33(32), 3894–3899. https://doi.org/10.1016/j.vaccine.2015.06.061

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