



MedImmune

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**FDA APPROVES EXPANDED LABEL FOR FLUMIST® TO INCLUDE
CHILDREN TWO TO FIVE YEARS OF AGE**

*First and Only Nasal Spray Influenza Vaccine for Young Children in U.S.
Available for 2007-2008 Flu Season*

GAITHERSBURG, MD, September 19, 2007 – MedImmune, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved the expanded use of FluMist® (Influenza Virus Vaccine Live, Intranasal) in children two to five years of age. FluMist is now approved for active immunization for the prevention of disease caused by influenza A and B viruses in individuals two to 49 years of age. Only one manufacturer had previously been licensed in the United States to produce influenza vaccine for children under four years of age.

MedImmune anticipates shipping FluMist with the expanded label to health care providers in the coming days so that vaccinations may be offered to eligible individuals ahead of and throughout the upcoming influenza season.

“As a company dedicated to innovative advancements in pediatric medicine, MedImmune is delighted to be able to offer FluMist as an option for children as young as two years old to help protect them from influenza,” said James F. Young, Ph.D., president, research and development. “With the new, refrigerated formulation approved in January, the results from our head-to-head study published in the February issue of *The New England Journal of Medicine*, and the expanded age indication now within the label, it is an exciting time for FluMist.”

In a pivotal study that included more than 4,000 children between the ages of two and five years of age during the 2004-2005 influenza season, there was a 54 percent reduction in cases of flu in children who received FluMist compared with those who received the traditional flu shot (4.5 percent vs. 9.8 percent, respectively).¹ In the study, FluMist demonstrated a reduction in influenza rates compared to the inactivated vaccine against strains that were both matched and mismatched to the vaccine.

¹ Data is representative of indicated population. Results for full study population are included in Prescribing Information.

In 48 completed clinical trials, more than 48,000 subjects ranging in age from six weeks to more than 90 years of age received FluMist. In addition to the clinical trial experience, approximately 60,000 doses of FluMist have been administered in two post-marketing studies, and approximately seven million doses of FluMist have been distributed for use in individuals five to 49 years of age following licensure of the product in 2003 through the 2006-2007 influenza season. FluMist is different from the flu shot in that it uses live, attenuated – or weakened – viruses within the vaccine to help stimulate an immune response that is designed to closely resemble the body’s natural response to an influenza infection.

“The FDA approval of FluMist for young children is important because these young kids have very high attack rates for influenza, often require medical evaluation for their influenza illness, and can spread influenza easily to others,” said Pedro Piedra, M.D., professor, Department of Molecular Virology and Microbiology, and Pediatrics, Baylor College of Medicine. “Also, the live attenuated influenza vaccine is quite effective in helping prevent influenza and is generally very acceptable to children and their parents since it is administered by nasal spray rather than a shot.”

Influenza’s Impact on Young Children

The flu is most prevalent in school-age children, as the virus travels easily from person to person and because children in this age group spend a large part of their day in close contact with other children. Children two to 17 years of age are twice as likely to get influenza than adults, including the elderly.² During a widespread outbreak, the rate of flu infections can exceed 30 percent in school-age children. Each year, up to 60 million Americans get the flu, according to the U.S. Centers for Disease Control and Prevention (CDC). Resulting complications cause more than 200,000 hospitalizations and approximately 36,000 deaths in the U.S. annually.

Protection Against Matched and Mismatched Strains of Flu

FluMist has demonstrated in clinical trials that it helps provide protection against flu strains both matched and mismatched to those used in the vaccine. Mismatched strains are circulating strains that are different from those included in manufacturing the season’s flu vaccines. According to CDC data, vaccine mismatch has occurred to varying degrees in five of the last 11 flu seasons, most recently during the 2005-2006 season.

About FluMist

FluMist is a live attenuated influenza virus vaccine indicated for active immunization of individuals two to 49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

FluMist is contraindicated in individuals with history of hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine or with life-threatening reactions to previous influenza vaccinations, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

² Glezen, W et al, *Influenza virus infections in infants*, 1997. *Pediatric Infectious Disease Journal*. 1997;16(11):1065-1068.

Do not administer FluMist to children less than two years of age due to an increased risk of hospitalization and wheezing that was observed in clinical trials. FluMist should not be administered to any individual with asthma and to children less than five years of age with recurrent wheezing unless the potential benefit outweighs the potential risk. Do not administer FluMist to individuals with severe asthma or active wheezing.

If Guillain-Barré syndrome has occurred with prior influenza vaccination or if an individual is immunocompromised, the decision to give FluMist should be based on careful consideration of the potential benefits and risks. FluMist should not be administered to individuals with underlying medical conditions predisposing them to wild-type influenza infection complications unless the potential benefit outweighs the potential risk. FluMist should be given to a pregnant woman only if clearly needed.

Most common adverse reactions (occurring in 10 percent or more of individuals receiving FluMist and at a rate at least five percent higher than in those receiving placebo) are runny nose or nasal congestion in recipients of all ages, fever more than 100° F in children two to six years of age, and sore throat in adults.

FluMist may not protect all individuals receiving the vaccine. FluMist is for intranasal administration only.

Please see complete Prescribing Information for FluMist, call 1-877-FLUMIST (1-877-358-6478) or visit www.flumist.com for additional information.

About MedImmune

MedImmune strives to provide better medicines to patients, new medical options for physicians and rewarding careers to employees. Dedicated to advancing science and medicine to help people live better lives, the company is focused on the areas of infectious diseases, cancer and inflammatory diseases. With approximately 3,000 employees worldwide and headquarters in Maryland, MedImmune is wholly owned by AstraZeneca plc (LSE: AZN.L, NYSE: AZN). For more information, visit MedImmune's website at <http://www.medimmune.com>.

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