

SUPPORTING INFECTIOUS DISEASE RESEARCH

Product Information Sheet for NR-36465

FluMist® Influenza Vaccine Live, Intranasal Spray, 2011-2012 Formula

Catalog No. NR-36465

This reagent is the property of the U.S. Government.

For research use only. Not for human use.

Contributor:

National Institutes of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

Manufacturer:

MedImmune, LLC

Product Description:

NR-36465 is a live, trivalent vaccine that produces the hemagglutinin and neuraminidase surface antigens from reassortant influenza viruses A/California/07/2009 (H1N1)pdm09, A/Perth/16/2009 (H3N2) B/Brisbane/60/2008 that were predicted to circulate in the United States during the 2011 to 2012 influenza season. The three viruses in NR-36465 are cold-adapted (ca). temperature-sensitive (ts) and attenuated (att). Each virus contains the two RNA segments encoding the hemagglutinin and neuraminidase from the antigenically relevant wild-type circulating strain. Each virus contains the six internal gene segments from a master donor virus responsible for the replication properties and the ca, ts and att phenotypes.

NR-36465 was prepared from virus propagated in the allantoic cavity of embryonated chicken eggs. The allantoic fluid was harvested, pooled and clarified by filtration. The virus was concentrated by ultracentrifugation and diluted with stabilizing buffer to obtain the final sucrose and potassium phosphate concentrations. Ethylene diamine tetracetic acid (EDTA) was added to the dilution buffer for the H3N2 strain. The viral harvests were sterile-filtered to produce monovalent bulks. The monovalent bulks were blended and diluted with stabilizing buffers to attain the desired potency and to produce the trivalent bulk vaccine. The bulk vaccine was then filled directly into individual sprayers for nasal administration.

Please note that this vaccine preparation is being released for research use only and not for human use.

Material Provided:

Each 0.2 mL single-use sprayer contains $10^{6.5}$ to $10^{7.5}$ fluorescent focus units of each of the three live, attenuated strains. Each sprayer also contains 0.188 mg monosodium glutamate, 2.00 mg hydrolyzed porcine gelatin, 2.42 mg arginine, 13.68 mg sucrose, 2.26 mg dibasic potassium phosphate, 0.96 mg monobasic potassium phosphate and < 0.015 μ g gentamicin sulfate. NR-36465 contains no preservatives.

Packaging/Storage:

NR-36465 consists of a pre-filled single-use (0.2 mL) sprayer. The product is provided on refrigerated bricks and should be stored at 2°C to 8°C immediately upon arrival. Do not freeze.

Citation:

Acknowledgment for publications should read "The following reagent was obtained through BEI Resources, NIAID, NIH: FluMist[®] Influenza Vaccine Live, Intranasal Spray, 2011-2012 Formula, NR-36465."

Biosafety Level: 1

Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the following publication: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: U.S. Government Printing Office, 2009; see www.cdc.gov/biosafety/publications/bmbl5/index.htm.

Disclaimers:

You are authorized to use this product for research use only. It is not intended for human use.

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References:

- Centers for Disease Control and Prevention (CDC). "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011." <u>MMWR Morb. Mortal Wkly. Rep.</u> 60 (2011): 1128-32. PubMed: 21866086.
- 2. www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094047.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=flumist&utm_content=1

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