Product Information Sheet for NR-15446

FLUARIX® Influenza Virus Vaccine, 2008-2009 Formula

Catalog No. NR-15446

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:

GlaxoSmithKline Biologicals

Product Description:

NR-15446 is a sterile suspension prepared from influenza viruses propagated in embryonated chicken eggs. Each of the influenza viruses was produced and purified separately. After harvesting the virus-containing fluids, each influenza virus was concentrated and purified by zonal centrifugation using a linear sucrose density gradient solution containing detergent to disrupt the viruses. Following dilution, the vaccine was further purified by diafiltration. Each influenza virus solution was inactivated by the consecutive effects of sodium deoxycholate and formaldehyde leading to the production of a "split virus." Each split inactivated virus was then suspended in sodium phosphate-buffered isotonic sodium chloride solution. The vaccine was formulated from the 3 split inactivated virus solutions.

The hemagglutinin content was standardized according to U.S. Public Health Service requirements. Each 0.5 mL syringe contains the recommended ratio of 15 µg each of the hemagglutinin antigens from influenza viruses A/Brisbane/59/2007 (H1N1)-like virus (A/Brisbane/59/2007 IVR-148), A/Brisbane/10/2007 (H3N2)-like virus (A/Uruguay/716/2007 NYMC X-175C) and B/Florida/4/2006-like virus (B/Brisbane/3/2007).

Each 0.5 mL of FLUARIX® also contains octoxynol-10 (TRITON® X-100; ≤ 0.12 mg), α-tocopheryl hydrogen succinate (≤ 0.1 mg) and polysorbate 80 (Tween 80; ≤ 0.38 mg). The vaccine was formulated without preservatives. Thimerosal was used at the early stages of manufacture but removed by subsequent purification steps to a trace amount (≤ 1 µg mercury per dose). Each dose may also contain residual amounts of hydrocortisone (≤ 0.0016 µg), gentamicin sulfate (≤ 0.15 µg), ovalbumin (≤ 1 µg), formaldehyde (≤ 50 µg) and sodium deoxycholate (≤ 50 µg) from the manufacturing process.

Please note that this vaccine preparation is being released for research use only and not for human use. Vaccines produced for the 2008-2009 season are now past their expiration dates.

Material Provided:

Each syringe contains 0.5 mL of split-virus vaccine in phosphate-buffered saline.

Packaging/Storage:

NR-15446 is packaged in a 0.5 mL prefilled syringe. 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 the NIH Biodefense and Emerging Infections Research Resources Repository, NIAID, NIH: FLUARIX® Influenza Virus Vaccine, 2008-2009 Formula, NR-15446."

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, 2007; see www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm.

Disclaimers:

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References:

1. Fiore, A. E., et al. "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008." MMWR Recomm. Rep. 59 (2010): 1-62. PubMed: 18685555.
2. WHO Recommendations for Influenza Vaccines

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