

# Influenza Vaccine (Fluarix Quadrivalent) Description

FLUARIX QUADRIVALENT, Influenza Vaccine, for intramuscular injection, is a sterile, colorless, and slightly opalescent suspension. FLUARIX QUADRIVALENT is prepared from influenza viruses propagated in embryonated chicken eggs. Each of the influenza viruses is produced and purified separately. After harvesting the virus-containing fluids, each influenza virus is concentrated and purified by zonal centrifugation using a linear sucrose density gradient solution containing detergent to disrupt the viruses. Following dilution, the vaccine is further purified by diafiltration. Each influenza virus solution is inactivated by the consecutive effects of sodium deoxycholate and formaldehyde leading to the production of a “split virus.” Each split inactivated virus is then suspended in sodium phosphate-buffered isotonic sodium chloride solution. Each vaccine is formulated from the split inactivated virus solutions.

FLUARIX QUADRIVALENT has been standardized according to U.S. Public Health Service (USPHS) requirements for the 2023-2024 influenza season and is formulated to contain 60 micrograms (mcg) hemagglutinin (HA) per 0.5-mL dose, in the recommended ratio of 15 mcg HA of each of the following 4 influenza virus strains (2 A strains and 2 B strains): A/Victoria/4897/2022 (H1N1) IVR-238, A/Darwin/6/2021 (H3N2) IVR-227 (an A/Darwin/9/2021 (H3N2)-like virus), B/Austria/1359417/2021 BVR-26 (B-Victoria lineage), and B/Phuket/3073/2013 (B-Yamagata lineage).

FLUARIX QUADRIVALENT is formulated without preservatives. FLUARIX QUADRIVALENT does not contain thimerosal. Each 0.5-mL dose also contains octoxynol-10 (TRITON X-100) 0.115 mg, octocopheryl hydrogen succinate 0.135 mg, and polysorbate 80 (Tween 80) 0.550 mg. Each dose may also contain residual amounts of hydrocortisone 0.0015 mcg, gentamicin sulfate 0.15 mcg, ovalbumin 0.050 mcg, formaldehyde 5 mcg, and sodium deoxycholate 65 mcg from the manufacturing process.

The tip caps and plungers of the prefilled syringes of FLUARIX QUADRIVALENT are not made with natural rubber latex.

To read the complete package insert of the FLUARIX QUADRIVALENT influenza vaccine, visit <https://www.fda.gov/media/79278/download>.