Press release

For media and investors only

Issued: 10 July 2025, Philadelphia, PA

GSK begins shipping influenza vaccine doses for the 2025-26 flu season

- GSK supports seasonal flu immunization in the US by shipping FLULAVAL (Influenza Vaccine) and FLUARIX (Influenza Vaccine) in advance of flu season

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GSK plc (LSE/NYSE: GSK) today announced it has started shipping doses of its trivalent seasonal influenza vaccines to US healthcare providers and pharmacies in preparation for the 2025-26 flu season. This immediately follows a licensing and lot-release approval from the US Food and Drug Administration (FDA). Both FLULAVAL and FLUARIX will be available in a 0.5mL, single-dose, pre-filled syringe and are indicated for people six months and older.

According to the US Centers for Disease Control and Prevention (CDC), annual influenza vaccination is the first and most important action recommended to reduce the risk of flu and its potentially serious outcomes. Ideally, vaccination should occur by the end of October, but people can continue to get vaccinated as long as the flu poses a threat.[1] CDC recommends an annual flu vaccination for anyone aged six months or older who does not have contraindications.[1,2]

CDC estimates that from October 1, 2024, through May 17, 2025, there were 47 – 82 million flu illnesses, 610,000 – 1.3 million flu hospitalizations and 27,000 – 130,000 flu deaths.[3] The 2024-25 flu season was the first season since 2017-18 that the CDC classified as high severity, and preliminary CDC estimates indicate that it was the worst flu season (based on flu illnesses, hospitalizations and deaths) the US has seen in the last 15 years.[4,5]

For egg-based influenza vaccines for the 2025-26 flu season in the Northern Hemisphere, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended including an A/Victoria/4897/2022 (H1N1)pdm09-like virus, an A/Croatia/10136RV/2023 (H3N2)-like virus and a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[6]

About Influenza

The flu is a contagious respiratory illness caused by influenza viruses that infect the nose, throat and sometimes the lungs. It can cause mild-to-severe illness and at times can lead to death.[7]

Anyone, including healthy people, can get the flu, however, it can be more serious for children younger than five, adults 65 years and older, people with a body mass index (BMI) of 40 kg/m^2 or higher, pregnant women and people with pre-existing chronic health conditions, such as asthma, diabetes and heart disease.[7]

For more information about the flu, visit https://www.cdc.gov/flu/about.

Indication for FLUARIX and FLULAVAL

FLUARIX and FLULAVAL are vaccines indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B virus contained in the vaccines. FLUARIX and FLULAVAL are approved for use in persons aged 6 months and older.

Important Safety Information for FLUARIX and FLULAVAL

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- Do not administer FLUARIX or FLULAVAL to anyone with a history of severe allergic reactions (eg, anaphylaxis) to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine.
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUARIX or FLULAVAL should be based on careful consideration of the potential benefits and risks.
- Syncope (fainting) can occur in association with administration of injectable vaccines, including FLUARIX and FLULAVAL. Procedures should be in place to avoid injury from fainting.
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUARIX and FLULAVAL.
- If FLUARIX or FLULAVAL is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons.
- The most common solicited local adverse reactions with FLUARIX in adults were pain and redness, and the most common systemic adverse reactions were muscle aches, fatigue, and headache. In children aged 5 through 17 years, the most common solicited local adverse reactions were pain, redness, and swelling, and the most common systemic adverse reactions were muscle aches, fatigue, and headache. In children aged 3 through 4 years, the most common solicited local adverse reactions were pain, redness, and swelling, and the most common systemic adverse reactions were irritability, loss of appetite, and drowsiness. In children aged 6 through 35 months who received FLUARIX QUADRIVALENT, the most common solicited local adverse reactions were pain and redness, and the most common systemic adverse reactions were irritability, loss of appetite, and drowsiness.
- The most common solicited local adverse reactions with FLULAVAL in adults were pain, redness, and swelling, and the most common solicited systemic adverse reactions were fatigue, headache, and muscle aches/arthralgia. In children aged 3 through 17 years, the most common solicited local adverse reaction was pain. In children aged 3 through 4 years, the most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite. In children aged 5 through 17 years, the most common solicited systemic adverse reactions were muscle aches, headache, and fatigue. In children aged 6 through 35 months who received FLULAVAL QUADRIVALENT, the most common solicited local adverse reaction was pain, and the most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite.
- Vaccination with FLUARIX or FLULAVAL may not result in protection of all vaccine recipients.

Please see full Prescribing Information for FLUARIX and for FLULAVAL.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2024.

Registered in England & Wales:

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