



Press release

For media and investors only

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GSK begins shipping influenza vaccine doses for 2024-25 season

- GSK supports annual flu immunization by getting FLULAVAL and FLUARIX to patients in advance of flu season

GSK plc (LSE/NYSE: GSK) today announced it has started shipping doses of its trivalent influenza vaccines to US healthcare providers and pharmacies in preparation for the 2024-25 flu season. This immediately follows a licensing and lot-release approval from the US Food and Drug Administration (FDA).

In February 2024, the World Health Organization (WHO) recommended the removal of B/Yamagata strains from seasonal influenza vaccines.¹ The WHO recommends that egg-based trivalent vaccines for the 2024-2025 northern hemisphere influenza season contain the following:¹

- A/Victoria/4897/2022 (H1N1)pdm09-like virus
- A/Thailand/8/2022 (H3N2)-like virus
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus

In partnership with regulatory bodies, GSK worked quickly to ensure production, approval and availability of trivalent influenza vaccines with the recommended composition for the 2024-25 flu season.

GSK expects to distribute over 36 million doses of its trivalent influenza vaccines in the US this season. Both FLULAVAL and FLUARIX will be available in a 0.5mL, single-dose, pre-filled syringe and are indicated for people six months of age and older.

According to the US Centers for Disease Control and Prevention (CDC), annual influenza vaccination is the best way to help protect against the flu. Ideally, vaccination should occur by the end of October, but people should continue to get vaccinated as long as the flu poses a threat.² CDC recommends an annual flu vaccination for anyone aged six months or older who does not have contraindications.²

CDC estimates that from October 1, 2023, through June 15, 2024, there have been 35 – 65 million flu illnesses, 390,000 – 830,000 flu hospitalizations and 25,000 – 72,000 flu deaths.³

About Influenza

The flu (influenza) 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.⁴

Anyone can get the flu, however, it can be serious for young children, adults 65 years and older, pregnant women and people with pre-existing chronic health conditions, such as asthma, diabetes and heart disease.⁵

For more information about the flu, visit <https://www.cdc.gov/flu/about/keyfacts.htm>.

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.



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Important Safety Information for FLUARIX and FLULAVAL

- 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 the company's Annual Report on Form 20-F for 2022, and Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

References

1. World Health Organization. Recommendations announced for influenza vaccine composition for the 2024-2025 northern hemisphere influenza season. Available at: <https://www.who.int/news/item/23-02-2024-recommendations-announced-for-influenza-vaccine-composition-for-the-2024-2025-northern-hemisphere-influenza-season>. Accessed June 17, 2024.
2. Centers for Disease Control and Prevention. Influenza (Flu) Preventative Actions. Available at: <https://www.cdc.gov/flu/prevent/prevention.htm>. Accessed June 17, 2024.
3. Centers for Disease Control and Prevention. 2023-2024 Preliminary In-Season Burden Estimates. Available at: <https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm>. Accessed June 17, 2024.
4. Centers for Disease Control and Prevention. Key Facts About Influenza (Flu). Available at: <https://www.cdc.gov/flu/about/keyfacts.htm>. Accessed June 17, 2024.
5. Centers for Disease Control and Prevention. About Flu. Available at: <https://www.cdc.gov/flu/about/index.html>. Accessed June 14, 2024.