



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Flucelvax

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Variation type II /	B.I.a.5 Changes to the active substance of a	04/07/2025	09/07/2025	SmPC,	B.I.a.5.a Replacement of the strain(s) in a seasonal,

¹ Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

² A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

³ SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



EMA/VR/0000272954	<p>seasonal, prepandemic or pandemic vaccine against human influenza - B.I.a.5.a</p> <p>Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza - Accepted</p> <p>Type II (B.I.a.5.a): Annual change in composition of Flucelvax in order to meet the WHO and EU recommendations for the upcoming Northern Hemisphere (NH) 2025/2026 Influenza season, as follows: • A/Georgia/12/2022 CVR-167 (an A/Wisconsin/67/2022 (H1N1)pdm09-like strain) • A/Victoria/800/2024 CVR-289 (an A/District of Columbia/27/2023 (H3N2)-like strain) • B/Singapore/WUH4618/2021 (a B/Austria/1359417/2021-like strain) The requested variation(s) proposed amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and Annex A.</p>			Labelling and PL	prepandemic or a pandemic vaccine against human influenza
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