Xofluza

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 / EMA/VR/0000323488		10/04/2026		SmPC and PL	

[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).

	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.8 of the SmPC in order to add ''ischaemic colitis'' to the list of adverse drug reactions (ADRs) with frequency ''Not Known'' based on the Drug Safety report 1142616. The Package Leaflet is updated accordingly.				
Variation type IA / EMA/VR/0000314429	Outcome: This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where	27/11/2025			

	no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.i Introduction of a new site of micronisation - Accepted				
Variation type II / EMA/VR/0000246160	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.8 and 5.1 of the SmPC in order to update clinical efficacy and safety information based on final results from study MV40618 (Centerstone), a phase 3b, multicenter, randomised, double-blind, placebo-controlled, clinical efficacy study of baloxavir marboxil for the reduction of direct transmission of influenza from otherwise healthy patients to household contacts. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and introduce editorial changes in the PI.	16/10/2025	17/11/2025	SmPC, Labelling and PL	In a phase 3b study of household influenza transmission, treatment emergent mutations, PA/I38M/N/T were detected in 15 of 208 influenza infected index patients (7.2 %) in the baloxavir marboxil group. For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000300791		25/09/2025			

	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted				
Renewal - 5 year / EMA/R/0000265299	Outcome: - Renewal - Accepted Renewal of marketing authorisation	18/09/2025	17/11/2025	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Xofluza in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Variation type IB / EMA/VR/0000284686	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1.b Extension of the shelf life of the	31/07/2025	17/11/2025	SmPC	

	finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Change in the holding time of an intermediate - Accepted				
PSUR / EMA/PSUR/0000274449	EURD: PSUSA/00010895/202502 Active substance: baloxavir marboxil	02/10/2025			

	Outcome: Maintenance				