EURneffy

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 IB /	Outcome:	01/06/2026			

[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/0000344107	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted Type IB, C.9.b – to propose an updated RMP as follows: - Table Part I.1 – Product Overview updated to proposed text approved in the previous version. - The list of all significant changes to the Risk Management Plan over time included in Annex 8 has been updated following approval of procedure EMA/X/0000248440.				
Variation type IA_IN / EMA/VR/0000348363	Outcome: Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted	28/05/2026		Annex II and PL	
Variation type IA / EMA/VR/0000323982	Outcome: This was an application for a group of variations.	03/02/2026			

	B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this				

	information. - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. - Accepted				
Extension of marketing authorisation / EMA/X/0000248440	Outcome: 2. Changes to strength, pharmaceutical form and route of administration - (c) change or addition of a new strength/potency - Accepted Extension application to introduce a new strength (1 mg nasal spray, solution). The new strength is indicated for children with a body weight of 15 kg to less than 30 kg.	29/01/2026	27/03/2026	SmPC, Labelling and PL	Please refer to the scientific discussion: EURneffy EMA/X/0000248440
Variation type IB / EMA/VR/0000264121	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.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted	06/05/2025			

Variation type IA_IN / EMA/VR/0000262105	Outcome: B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	26/03/2025	27/03/2026	Annex II and PL	
PSUR / EMA/PSUR/0000269019	EURD: PSUSA/00011081/202502 Active substance: epinephrine (for nasal use) Outcome: Maintenance	04/09/2025			Maintenance
PSUR / EMA/PSUR/0000311165	EURD: PSUSA/00011081/202508 Active substance: epinephrine (for nasal use) Outcome: Maintenance	12/03/2026			Maintenance