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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 /	C.I HUMAN AND VETERINARY MEDICINAL	11/09/2025		SmPC and PL	Section 4.5 subsection Potential of other medicinal

[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/0000255116	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 4.5 and 5.2 of the SmPC in order to update pharmacokinetic and drug-drug interaction information based on final results from the DDI study CBAF312A02101; this is an open-label, non-randomized, three-period, single-sequence crossover study to evaluate the effect of the CYP3A4 inhibitor clarithromycin on siponimod (BAF312) single dose pharmacokinetics, safety, and tolerability in healthy participants with a CYP2C9*1*3 genotype. The Package Leaflet is updated accordingly.				products to affect siponimod pharmacokinetics: CYP2C9 inhibitors and CYP2C9 and CYP3A4 inducers has been updated based on final results from the DDI study CBAF312A02101. Section 5.2 subsection biotransformation as also been updated based on results from the same study. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000273065	This was an application for a group of variations. C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.a Implementation of wording agreed by the competent authority - Accepted C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing	12/08/2025		Annex II	To update the RMP regarding the HCP checklist and patient/caregiver guide concerning IRIS after discontinuation of siponimod due to PML. Moreover, the information about the signs and symptoms to identify cases of hepatic events is updated in the patient/caregivers guide according to the information already included in the package leaflet. Also the secondary objectives of CBAF312A2411, Pregnancy outcomes Intensive Monitoring (PRIM) are updated as well update of information on “Safety in patients over 60 years old” and “Use during lactation”, and addition of “Malignant

	authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted To update the RMP regarding the HCP checklist and patient/caregiver guide concerning IRIS after discontinuation of siponimod due to PML. Moreover, the information about the signs and symptoms to identify cases of hepatic events is updated in the patient/caregivers guide according to the information already included in the package leaflet. Also the secondary objectives of CBAF312A2411, Pregnancy outcomes Intensive Monitoring (PRIM) are updated as well update of information on "Safety in patients over 60 years old" and "Use during lactation", and addition of "Malignant Melanoma" to important identified risks (with consequent change in name of important potential risk from "Malignancies (except for BCC, SCC)" to "Malignancies (except for BCC, SCC and malignant melanoma)," update Key Safety Messages (KSM) about IRIS in Physician's checklist and in patient/caregiver's guide, remove KSM regarding hepatic signs and symptoms from patient/caregiver's guide, update pregnancy KSM in Physician's checklist and pregnancy reminder card. Annex II has been updated in line with this				Melanoma" to important identified risks (with consequent change in name of important potential risk from "Malignancies (except for BCC, SCC)" to "Malignancies (except for BCC, SCC and malignant melanoma)," update Key Safety Messages (KSM) about IRIS in Physician's checklist and in patient/caregiver's guide, remove KSM regarding hepatic signs and symptoms from patient/caregiver's guide, update pregnancy KSM in Physician's checklist and pregnancy reminder card. Annex II has been updated in line with this update in RMP Annex 6.

	update in RMP Annex 6.				
Variation type IB / EMA/VR/0000271737	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	26/06/2025	N/A		