AQUIPTA

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. Safety, efficacy, pharmacovigilance	09/07/2026		SmPC	Update of section 5.1 of the SmPC in order to

[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/0000334780	changes - C.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 5.1 of the SmPC in order to update long term safety, tolerability and efficacy information based on final results from study 3101-312-002 listed as a category 3 study in the RMP; this is a phase 3, multicenter, open-label, 156-week extension study to evaluate the long-term safety and tolerability of oral atogepant for the prevention of migraine in participants with chronic or episodic migraine. The RMP version 3.0 has also been approved.				update long term safety, tolerability and efficacy information based on final results from study 3101-312-002.
Variation type II / EMA/VR/0000310717	This was an application for a group of variations. C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	23/04/2026	29/05/2026	SmPC, Labelling and PL	Please refer to Scientific Discussion EMA/VR/0000310717.

	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted				
Variation type II / EMA/VR/0000315259	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 section 5.1 of the SmPC based on the primary analysis of results from TEMPLE study M22-061. This is a randomized, double-blind, parallel-group, active controlled trial with open-label safety extension to evaluate the Tolerability, Safety, and Efficacy of Atogepant versus Topiramate, in subjects requiring preventive treatment of migraine.	10/04/2026	29/05/2026	SmPC	Update of the section 5.1 of the SmPC based on the primary analysis of results from TEMPLE study M22-061. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000302639	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	27/10/2025			
Variation type IB / EMA/VR/0000272651	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate /	02/06/2025			

	reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted				
Variation type IA / EMA/VR/0000266446	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	23/04/2025			
Variation type IB / EMA/VR/0000248370	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.e Site where any	07/03/2025			

	manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - 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.a Minor change in the manufacturing process - Accepted B.II.a.3 Changes in the composition (excipients) of the finished product - B.II.a.3.z Other changes - Accepted				
PSUR / EMA/PSUR/0000321517	EURD: PSUSA/00000100/202509 Active substance: atogepant Outcome: Maintenance	07/05/2026			Maintenance
PSUR / EMA/PSUR/0000282279	EURD: PSUSA/00000100/202503 Active substance: atogepant Outcome: Maintenance	30/10/2025			Maintenance