Ruconest

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 /	Outcome:	07/05/2026			

[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/0000326016	C. Safety, efficacy, pharmacovigilance changes - C.12 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies, including be to be d. bioequivalence studies, to the competent authority - Accepted Submission of the final report from study PHARM/EU/aRMM/01 listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS concerning additional risk minimization measures for Ruconest – European survey of educational materials. The RMP version 22.0 has also been submitted.				
Variation type II / EMA/VR/0000263304	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from Ruconest EU registry listed as a category 3 study in the RMP. This is a non-imposed non-interventional PASS (phase IV) of C1 inhibitor Treatment Registry to assess the Safety and Immunological Profile of Ruconest in the treatment of HAE Attacks. Version 21.0 of the RMP has also been submitted.	27/11/2025			

Variation type IB / EMA/VR/0000267751	Outcome: B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	22/05/2025			
PSUR / EMA/PSUR/0000248470	EURD: PSUSA/00000873/202410 Active substance: conestat alfa Outcome: Maintenance	05/06/2025			Maintenance
PSUR / EMA/PSUR/0000288246	EURD: PSUSA/00000873/202504 Active substance: conestat alfa Outcome: Maintenance	27/11/2025			Maintenance