Kineret

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/0000249038	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics,	04/09/2025		SmPC and PL	During post-marketing use, drug reaction with eosinophilia and systemic symptoms (DRESS) has rarely been reported in patients treated with

[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).

	Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4, and 4.8 of the SmPC in order to include updated information on Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) following post-marketing safety surveillance; the Package Leaflet is updated accordingly. The RMP version 6.3 has also been submitted. In addition, the MAH took the opportunity to correct editorial errors and to include wording regarding excipient polysorbate 80 in accordance with the updated annex to the European Commission guideline in the PI.				Kineret, predominantly in paediatric patients with Still's disease [systemic juvenile idiopathic arthritis (SJIA)]. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000261578	This was an application for a group of variations. B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for	15/05/2025	N/A		

	batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - 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 no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted				
Variation type IA_IN / EMA/VR/0000262380	This was an application for a group of variations. A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality	03/04/2025	N/A		

	control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted 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.a Secondary packaging site - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
Variation type IA_IN / EMA/VR/0000232908	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	31/10/2024	N/A		