Omjjara

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 IA_IN /	Outcome:	20/04/2026			

[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/0000342197	Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted				
Variation type II / EMA/VR/0000307131	Outcome: 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 of section 4.8 of the SmPC in order to add erythema multiforme and hypersensitivity to the list of adverse drug reactions (ADRs) based on postmarketing data. The Package Leaflet is updated accordingly. In addition, the MAH implement editorial changes to the PI.	10/04/2026		SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000316442	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - to provide the determination of partition coefficient study report in support of the environmental risk assessment.	23/02/2026			

Variation type II / EMA/VR/0000316334	Outcome: This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted A grouped application consisting of: C.I.13: Submission of the final report from non-clinical study 2025N566140/01: Biochemical characterization of momelotinib, M21, M19 and M8. C.I.13: Submission of the final report from non-clinical study 2025N567886/00: Integration of Biochemical, Biophysical, and Cellular Assay Results to Identify Kinases Inhibited by Momelotinib and its Major Metabolite M21 at clinically relevant concentrations. C.I.13: Submission of the final report from non-clinical study 2025N568681/00: Evaluation of kinases inhibited by Momelotinib (MMB) and M21 at clinically relevant concentrations.	12/02/2026			Not applicable

Variation type IA / EMA/VR/0000291857	Outcome: B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted	18/08/2025			

	B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.b Downscaling down to 10-fold - Accepted				
PSUR / EMA/PSUR/0000317675	EURD: PSUSA/00000263/202509 Active substance: momelotinib Outcome: Maintenance	10/04/2026			Maintenance
PSUR / EMA/PSUR/0000274423	EURD: PSUSA/00000263/202503 Active substance: momelotinib Outcome: Maintenance	02/10/2025			Maintenance