FRUZAQLA

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 IB / EMA/VR/0000357160	Outcome: Q.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State for active substances, reagents,	01/07/2026			

[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).

	intermediates, excipients, immediate packaging materials and active substance starting materials(*) - Q.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted				
Variation type IB / EMA/VR/0000339669	Outcome: Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted	12/05/2026		SmPC	
PSUR / EMA/PSUR/0000317678	EURD: PSUSA/00011069/202509 Active substance: fruquintinib Outcome: Maintenance	10/04/2026			Maintenance
Variation type IB / EMA/VR/0000313793	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	12/12/2025			
Variation type IB / EMA/VR/0000291462	Outcome: B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - Accepted	28/08/2025			

Variation type IA / EMA/VR/0000248904	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active	13/02/2025			

	substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
PSUR / EMA/PSUR/0000274462	EURD: PSUSA/00011069/202503 Active substance: fruquintinib Outcome: Maintenance	02/10/2025			Maintenance