QINLOCK

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:	09/07/2026		SmPC and PL	SmPC new text: Section 4.5: Interaction with other

[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/0000343405	C. Safety, efficacy, pharmacovigilance 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 4.5 of the SmPC in order to update drug interaction information based on results from study DCC-2618-01-010. This is a Phase 1 Open-label Study to Evaluate the Effect of Ripretinib on the Pharmacokinetics of a Sensitive CYP3A Probe Substrate (Midazolam) in Patients with Advanced Gastrointestinal Stromal Tumor (GIST). The Package Leaflet is updated in accordance.				medicinal products and other forms of interaction Effect of ripretinib on other medicinal products - CYP isoform-selective Co-administration of QINLOCK with midazolam (a sensitive probe substrate for CYP3A4) did not impact the pharmacokinetics of midazolam and 1-hydroxy midazolam; therefore, dose adjustment is not required when QINLOCK is co-administered with CYP3A4 substrates.
Renewal - 5 year / EMA/R/0000326982	Outcome: Renewal of marketing authorisation	21/05/2026	29/07/2026	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of QINLOCK in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity
Variation type IA_IN / EMA/VR/0000326560	Outcome: This was an application for a group of variations. E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank,	11/02/2026	29/07/2026	SmPC, Annex II, Labelling and PL	

	manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.a) The change in the name and/or address concerns the marketing authorisation holder - Accepted E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.b) The change in the name and/or address concerns a manufacturer(s)whose activities include batch release of the finished product - Accepted				
Variation type IB / EMA/VR/0000296456	Outcome: B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	07/10/2025			

Variation type IB / EMA/VR/0000296131	Outcome: B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	02/10/2025			
Variation type II / EMA/VR/0000284381	Outcome: This was an application for a group of variations. 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 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 A grouped application consisting of: C.I.4: Update of section 4.5 of the SmPC based on results from drug-drug interaction study DCC-2618-01-007. In addition, the MAH took the opportunity to implement editorial changes to the PI, as well as, to update the list of representatives in the Packagae Leaflet. C.I.4: Update of section 4.5 of the	11/09/2025	29/07/2026	SmPC and PL	SmPC new text Section 4.5: Interaction with other medicinal products and other forms of interaction CYP isoform-selective substrates Ripretinib is a weak inhibitor of CYP2C8. Co-administration of QINLOCK with repaglinide (a sensitive index substrate for CYP2C8) increased repaglinide AUC0-∞ by 26%. Repaglinide Cmax was unchanged; therefore, dose adjustment is not required. UGT1A substrates In vitro studies suggested that ripretinib is an inhibitor of UGT1A1, UGT1A3, UGT1A4, UGT1A7, and UGT1A8. QINLOCK is to be used with caution in combination with clinical substrates of UGT1A enzymes (e.g. bictegravir, cabotegravir, dolutegravir, raltegravir, lamotrigine), as co-administration may lead to increased exposure of these substrates. Clinical studies with UGT1A substrates have not been conducted. Section 4.8: The frequency of Grade 3 decreased left ventricular ejection fraction in the pooled safety population was corrected to 2 % (previously 4 %). For more information, please refer to the Summary of Product Characteristics.

	SmPC based on results from in vitro study DCC-2618-03-0046 to investigate the interaction between QINLOCK and UGT1A substrates.				
Variation type IB / EMA/VR/0000278855	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - to provide an updated Environmental Risk Assessment report.	08/08/2025			
Variation type IA / EMA/VR/0000286650	Outcome: This was an application for a group of variations. 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 B.III.2.a Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.a.2 Excipient/active substance starting material - Accepted	17/07/2025			
Variation type IB / EMA/VR/0000271896	Outcome: B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-significant in-process test - Accepted	23/05/2025			

Variation type IB / EMA/VR/0000261098	Outcome: 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.z Other changes - Accepted	28/03/2025			
PSUR / EMA/PSUR/0000288238	EURD: PSUSA/00010962/202505 Active substance: ripretinib Outcome: Maintenance	27/11/2025			Maintenance