Cibinqo

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
PSUSA/10976 /202409	Periodic Safety Update EU Single assessment - abrocitinib	25/04/2025	23/06/2025	SmPC and PL	Please refer to Cibinqo-EMEA/H/C/PSUSA/00010976/202409 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0021	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/10/2024	23/06/2025	SmPC	

[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).

IB/0020	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/10/2024	n/a		
PSUSA/10976 /202403	Periodic Safety Update EU Single assessment - abrocitinib	03/10/2024	n/a		PRAC Recommendation - maintenance
IB/0018	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	20/08/2024	23/06/2025	SmPC	
PSUSA/10976 /202309	Periodic Safety Update EU Single assessment - abrocitinib	11/04/2024	n/a		PRAC Recommendation - maintenance
IA/0016	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	05/04/2024	n/a		
II/0010	Extension of indication to include treatment of adolescents 12 to < 18 years of age with moderate to severe atopic dermatitis for CIBINQO based on final results from non-clinical study 00655292 [21GR211] and interim results from clinical study B7451015; this is a Phase III multi-center, long-term extension study investigating the efficacy and safety of abrocitinib, with or without topical medicines, administered to subjects aged 12 years and older with moderate to severe atopic dermatitis. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Furthermore, the PI is	22/02/2024	21/03/2024	SmPC and PL	Please refer to Scientific Discussion 'Cibinqo-H-C-005452-II-Var.0010'.

	brought in line with the latest QRD template version 10.3. The RMP (version 4.4) is acceptable. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IAIN/0015	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	21/02/2024	21/03/2024	Annex II and PL	
IA/0013/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	05/10/2023	n/a		
IA/0012	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	05/10/2023	n/a		

PSUSA/10976 /202303	Periodic Safety Update EU Single assessment - abrocitinib	28/09/2023	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	28/06/2023	25/01/2024	SmPC	
PSUSA/10976 /202209	Periodic Safety Update EU Single assessment - abrocitinib	14/04/2023	n/a		PRAC Recommendation - maintenance
IA/0008	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/04/2023	n/a		
A20/0003	Pursuant to Article 20 of Regulation (EC) No 726/2004, the European Commission requested on 28 January 2022 the opinion of the European Medicines Agency further to the safety issues on MACE, VTE, serious infections, malignancy and mortality for all JAK inhibitors used in the treatment of inflammatory disorders. The CHMP was requested to assess the impact thereof on the benefit-risk balance of Cibinqo, Jyseleca, Olumiant, Rinvoq and Xeljanz and to give its recommendation whether the marketing authorisation of this product should be maintained, varied, suspended or revoked. As the request results from the evaluation of data resulting from pharmacovigilance activities, the CHMP opinion was adopted on the basis of a recommendation of the Pharmacovigilance Risk Assessment Committee.	23/01/2023	10/03/2023	SmPC, Annex II and PL	Please refer to the assessment report: Cibinqo (abrocitinib) EMEA/H-A20/1517/C/005452/0003

II/0007	To update section 5.1 of the SmPC in order to update long-term efficacy data based on the results from studies B7451012, B7451013, B7451015 and B7451029. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/02/2023	25/01/2024	SmPC	SmPC section 5.1 has been revised to update the long-term efficacy data. Efficacy data through Week 96 of cumulative treatment demonstrated that most initial responders maintained their response through Week 96. The response to abrocitinib treatment decreased slightly over time through Week 48 among subjects who achieved initial response at Week 12. However, there was no clinically meaningful decrease in IGA, EASI-75, or PP-NRS4 response rate between Week 48 and Week 96. Efficacy data through 96 weeks of cumulative treatment continue to support the long-term efficacy of both abrocitinib 100 mg QD and 200 mg QD in the treatment of adult patients with moderate-to-severe AD. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10976 /202203	Periodic Safety Update EU Single assessment - abrocitinib	29/09/2022	n/a		PRAC Recommendation - maintenance
II/0005	Update of section 4.5 of the SmPC based on final results from Drug-Drug Interaction (DDI) study B7451092. This is a Phase I, open-label, fixed-sequence, 2-period study to estimate the effect of multiple dose abrocitinib on the pharmacokinetics of single doses of caffeine, efavirenz, and omeprazole in healthy participants. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	08/09/2022	10/03/2023	SmPC	The effect of abrocitinib on CYP1A2, 2B6, and 2C19 enzymes was assessed in vivo. Abrocitinib is a moderate inhibitor of CYP2C19 enzyme; caution should thus be exercised when using abrocitinib concomitantly with narrow therapeutic index medicines that are primarily metabolised by CYP2C19. Further, abrocitinib is also a mild inhibitor of CYP1A2 enzyme, nevertheless no general dose adjustment can be recommended. For more information, please refer to the Summary of Product Characteristics.

	data				
II/0001	Update of sections 4.4 and 4.8 of the SmPC based on updated safety data from the Full Cumulative Pool (April 2021 data cut) from the ongoing long-term extension study B7451015.The RMP version v1.0 has also been submitted. In addition, MAH took the opportunity to implement editorial changes in the SmPC and to update the contact details of the local representatives in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/09/2022	10/03/2023	SmPC and PL	Based on updated safety data from the Full Cumulative Pool (April 2021 data cut) from the ongoing long-term extension study B7451015, SmPC sections 4.4 and 4.8 of the SmPC were updated. It was highlighted in SmPC section 4.4 that tuberculosis was observed in clinical studies with abrocitinib; and in SmPC sections 4.4 and 4.8 that the rate of herpes zoster infections was higher in patients who were treated with 200 mg, with a medical history of herpes zoster, with a confirmed ALC < 1 × 103/mm3 prior to the event. For more information, please refer to the Summary of Product Characteristics.
II/0002	Update of sections 4.2 and 4.5 of the SmPC based on results from Drug-Drug Interaction (DDI) study B7451061; A phase 1, randomised, crossover study to evaluate relative bioavailability of abrocitinib oral suspension and effect of an acid-reducing agent on the bioavailability of abrocitinib commercial tablet and to assess the taste of abrocitinib oral formulations in healthy adult participants aged 18 to 55 years of age. The Package Leaflet is updated in accordance. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	07/07/2022	10/03/2023	SmPC	When abrocitinib 200 mg was administered concomitantly with famotidine 40 mg, an H2-receptor antagonist, abrocitinib active moiety exposures decreased by approximately 35%. The effect of elevating gastric pH with antacids, or proton pump inhibitors (omeprazole) on the pharmacokinetics of abrocitinib has not been studied and may be similar to that seen with famotidine. Therefore, the higher 200 mg daily dose should be considered for patients treated concomitantly with products which increase gastric pH, as they may reduce the efficacy of abrocitinib. For more information, please refer to the Summary of Product Characteristics.