QUVIVIQ

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
IA/0015	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	22/04/2024		SmPC	
II/0013/G	This was an application for a group of variations. Update of sections 4.4, 4.6 and 5.1 of the SmPC in	11/04/2024		SmPC and PL	Update of sections 4.4, 4.6 and 5.1 of the SmPC in order to reflect the conclusions of studies ID-075-121, ID-078-122 and ID-078-118, respectively. The Package Leaflet was

[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).

	order to reflect the conclusions of studies ID-075-121, ID-078-122 and ID-078-118, respectively. The Package Leaflet was updated accordingly. Study ID-078-121 is a randomized, double-blind, placebo-controlled, 2-way crossover study to investigate the effects of daridorexant on nighttime respiratory function and sleep in subjects with severe obstructive sleep apnea; Study ID-078-122 is a prospective, open-label, single-dose Phase 1 study to measure daridorexant in breast milk of healthy lactating women; and Study ID-078-118 is a single-center, randomized, double-blind, single-dose, 3-way crossover study to compare the effects of daridorexant and placebo on postural stability, the auditory awakening threshold, and cognitive function in the middle of the night following evening administration to healthy adult and elderly subjects. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				updated accordingly. Study ID-078-121 is a randomized, double-blind, placebo-controlled, 2-way crossover study to investigate the effects of daridorexant on nighttime respiratory function and sleep in subjects with severe obstructive sleep apnea; Study ID-078-122 is a prospective, open-label, single-dose Phase 1 study to measure daridorexant in breast milk of healthy lactating women; and Study ID-078-118 is a single-center, randomized, double-blind, single-dose, 3-way crossover study to compare the effects of daridorexant and placebo on postural stability, the auditory awakening threshold, and cognitive function in the middle of the night following evening administration to healthy adult and elderly subjects.
PSUSA/10993 /202307	Periodic Safety Update EU Single assessment - daridorexant	08/02/2024	n/a		PRAC Recommendation - maintenance

PSUSA/10993 /202301	Periodic Safety Update EU Single assessment - daridorexant	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0011/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	11/07/2023	n/a		
II/0009/G	This was an application for a group of variations. Update of section 4.5 of the SmPC in order to add drug-drug interaction information with midazolam, dabigatran, rosuvastatin and warfarin, based on studies ID-078-125 and ID-078-126. Study ID-078-125 is a single-centre, open-label, three-period,	12/05/2023		SmPC and PL	For more information, please refer to the Summary of Product Characteristics.

	fixed-sequence design study to investigate the effect of daridorexant on the pharmacokinetics of dabigatran and rosuvastatin in healthy male subjects, while study ID-078-126 is a single-centre, open-label study to investigate the effect of single- and multiple-dose daridorexant on the pharmacokinetics of midazolam and its metabolite 1-hydroxymidazolam, and the effect of single-dose daridorexant on the pharmacokinetics and pharmacodynamics of warfarin in healthy male subjects. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0007/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting	30/03/2023	n/a		

	material/intermediate/reagent - Other variation B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier				
IB/0008	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)	15/03/2023	26/05/2023	SmPC	

PSUSA/10993 /202207	Periodic Safety Update EU Single assessment - daridorexant	09/02/2023	n/a		PRAC Recommendation - maintenance
IAIN/0006	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	11/11/2022	26/05/2023	Annex II and PL	
II/0004/G	This was an application for a group of variations. Submission of the final report from studies BA-17.030 (Validation of an analytical method for the determination of ACT-541468 and its metabolites ACT-776063, ACT-776537 and ACT-1016-3307 in rat plasma samples by LC-MS/MS) and Study BA-18.023 (Validation of an analytical method for the determination of ACT-541468 and its metabolites ACT-776063, ACT-776537 and ACT-1016-3307 in rabbit plasma samples by LC-MS/MS). Both studies are part of the same post-authorisation measure evaluating the long-term stability of daridorexant and its metabolites (ACT-776063, ACT776537 and ACT-1016-3307) in rat and rabbit. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	08/09/2022	n/a		

N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/07/2022	26/05/2023	PL	
IAIN/0002	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	02/06/2022	26/05/2023	SmPC, Labelling and PL	
IAIN/0001/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	02/06/2022	26/05/2023	SmPC, Labelling and PL	