Moventig

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/10317 /202409	Periodic Safety Update EU Single assessment - naloxegol	10/04/2025	n/a		PRAC Recommendation - maintenance
II/0043	Submission of the final report from the PASS study D3820R0008 listed as a category 3 study in the RMP. This is a US post-marketing, comparative, observational study to evaluate the cardiovascular safety of Naloxegol in patients with non-cancer pain in comparison to other treatments for opioid induced constipation. The RMP version 9.0 has also been submitted.	28/11/2024	n/a		

[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).

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0046	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	27/11/2024		SmPC, Labelling and PL	
IAIN/0045	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	17/09/2024		Annex II and PL	
T/0044	Transfer of Marketing Authorisation	14/03/2024	15/04/2024	SmPC, Labelling and PL	
PSUSA/10317 /202309	Periodic Safety Update EU Single assessment - naloxegol	11/04/2024	n/a		PRAC Recommendation - maintenance
II/0039	Update of sections 4.2 and 4.4 of the SmPC based on real-world data from non-interventional studies (NACASY, KYONAL and MOVE studies), post-marketing data, and literature on the use of naloxegol in OIC patients with cancer-related pain. The Package Leaflet is updated accordingly. The RMP version 8.2 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	09/11/2023	11/12/2023	SmPC and PL	Please refer to Scientific Discussion 'Moventig H/C/002810/II/0039

	modification of an approved one				
PSUSA/10317 /202209	Periodic Safety Update EU Single assessment - naloxegol	14/04/2023	n/a		PRAC Recommendation - maintenance
IB/0041/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	24/03/2023	n/a		
II/0038	Submission of an updated RMP version 7.2 proposing the cancellation of the cat. 3 study (D3820R00009:	07/07/2022	n/a		

	An Observational Drug Utilisation PASS of Moventig in selected European populations), following the assessment of MEA 006.11. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/10317 /202109	Periodic Safety Update EU Single assessment - naloxegol	07/04/2022	n/a		PRAC Recommendation - maintenance
II/0034	Submission of the final report from the observational Post Authorization Safety Study (PASS)- Drug Utilisation in Selected European Populations (D3820R00006), listed as a category 3 study in the Risk Management Plan (RMP). The RMP version 7.1 is accepted. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	13/01/2022	n/a		This variation concerns the final study report of the observational Post-authorization Safety Study (PASS) D3820R00006, to describe the utilization of naloxegol within a cohort of adult patients with opioid induced constipation (OIC). This study data provided insights into the demographics of naloxegol users, the utilisation of naloxegol in the general population (United Kingdom, Norway, Sweden and Germany) population with contraindications, potential off-label use, and the use in vulnerable/special populations (patients aged ≥65 years; pregnant; patients with prior cardiovascular disease; patients with prior renal or hepatic impairment; patients with concurrent methadone use; and patients with concurrent use of cytochrome P450 [CYP] 3A inhibitors/inducers or P-glycoprotein [Pgp] modulators). Overall, no new safety concerns were raised in this study. The RMP is updated accordingly (version 7.1) to remove

					reference to study D3820R00006.
IB/0035	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	10/01/2022	n/a		
IA/0037	A.7 - Administrative change - Deletion of manufacturing sites	17/12/2021	16/12/2022	Annex II and PL	
PSUSA/10317 /202009	Periodic Safety Update EU Single assessment - naloxegol	09/04/2021	n/a		PRAC Recommendation - maintenance
II/0029/G	This was an application for a group of variations. Submission of an updated RMP version 6.1 in order to update the list of safety concerns. C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	04/09/2020	n/a		In this group of variations the MAH updated the list of safety concerns in line with recommendations given in GVP Module V and reclassified "GI perforation" as an important identified risk in order to implement the outcomes of the PRAC recommendation given in EMEA/H/C/PSUSA/00010317/201809 and following the PI amendments undertaken in this PSUR. The MAH also took the opportunity to include updated exposure data, updated analyses of the safety concerns and preliminary results from the additional pharmacovigilance activities.
PSUSA/10317 /201909	Periodic Safety Update EU Single assessment - naloxegol	17/04/2020	n/a		PRAC Recommendation - maintenance

IAIN/0031	B.II.g.3 - Deletion of an approved change management protocol related to the finished product	13/11/2019	n/a		
IAIN/0030/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.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 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 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	18/10/2019	09/10/2020	Annex II and PL	
R/0028	Renewal of the marketing authorisation.	25/07/2019	23/09/2019	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Moventig in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

PSUSA/10317 /201809	Periodic Safety Update EU Single assessment - naloxegol	26/04/2019	20/06/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10317/201809.
IA/0027/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	13/02/2019	20/06/2019	SmPC and PL	
PSUSA/10317 /201803	Periodic Safety Update EU Single assessment - naloxegol	18/10/2018	12/12/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10317/201803.
IB/0025	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/10/2018	20/06/2019	SmPC, Labelling and PL	
IB/0024	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g.	07/08/2018	12/12/2018	SmPC, Labelling and	

	tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes			PL	
T/0023	Transfer of Marketing Authorisation	02/07/2018	23/07/2018	SmPC, Labelling and PL	
PSUSA/10317 /201709	Periodic Safety Update EU Single assessment - naloxegol	12/04/2018	n/a		PRAC Recommendation - maintenance
IB/0021	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)	29/01/2018	23/07/2018	SmPC	
IB/0020/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	20/12/2017	23/07/2018	Annex II and PL	

	Replacement/addition of a site where batch control/testing takes place 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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
PSUSA/10317 /201703	Periodic Safety Update EU Single assessment - naloxegol	12/10/2017	08/12/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10317/201703.
IAIN/0019/G	This was an application for a group of variations. 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.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.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	07/12/2017	23/07/2018	SmPC, Labelling and PL	

IB/0016	B.III.1.z - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Other variation	18/10/2017	n/a		
IA/0017/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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	09/10/2017	n/a		
IA/0015/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	05/07/2017	n/a		

N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/04/2017	08/12/2017	Labelling and PL	
PSUSA/10317 /201609	Periodic Safety Update EU Single assessment - naloxegol	06/04/2017	n/a		PRAC Recommendation - maintenance
T/0011	Transfer of Marketing Authorisation	02/09/2016	30/09/2016	SmPC, Labelling and PL	
PSUSA/10317 /201603	Periodic Safety Update EU Single assessment - naloxegol	29/09/2016	n/a		PRAC Recommendation - maintenance
II/0007	Update of sections 4.2 and 5.2 of the SmPC and section 3 of the PL, to provide information about the use of crushed tablets mixed in water and administered orally or via nasogastric tube. In addition, the Marketing authorisation holder (MAH) took the opportunity to combine the SmPCs for 12,5 mg and 25 mg and to bring the PI in line with the latest QRD template version 9.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/04/2016	30/09/2016	SmPC, Annex II and PL	
PSUSA/10317 /201509	Periodic Safety Update EU Single assessment - naloxegol	14/04/2016	n/a		PRAC Recommendation - maintenance
II/0009	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/04/2016	n/a		

IAIN/0008/G	This was an application for a group of variations. 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.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	15/01/2016	n/a		
IA/0006/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	17/12/2015	n/a		
II/0003	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	10/12/2015	n/a		

IG/0633	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	09/12/2015	n/a		
PSUSA/10317 /201503	Periodic Safety Update EU Single assessment - naloxegol	08/10/2015	n/a		PRAC Recommendation - maintenance
IB/0001/G	This was an application for a group of variations. B.II.g.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supporting data B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.I.c.z - Container closure system of the AS - Other variation B.I.c.z - Container closure system of the AS - Other variation	24/03/2015	n/a		