BUCCOLAM

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
II/0061	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	19/09/2024	21/10/2024	SmPC, Labelling and PL	
IAIN/0067/G	This was an application for a group of variations.	21/10/2024	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).

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	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 A.7 - Administrative change - Deletion of manufacturing sites				
IB/0066/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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	20/09/2024	n/a		
IB/0064/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	11/09/2024	n/a		

	or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate 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 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.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.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)				
IAIN/0065	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	05/08/2024	n/a		
IB/0063	B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	21/06/2024	21/10/2024	SmPC and PL	
N/0060	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/01/2024	22/05/2024	PL	
PSUSA/10118 /202209	Periodic Safety Update EU Single assessment - midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)	26/04/2023	07/07/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10118/202209.
IAIN/0059/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.1 - Administrative change - Change in the name and/or address of the MAH	21/06/2023	22/05/2024	SmPC, Annex II, Labelling and PL	

	A.7 - Administrative change - Deletion of manufacturing sites				
N/0058	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/02/2023	07/07/2023	PL	
IB/0056	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/10/2022	07/07/2023	SmPC and PL	To update section 4.4 of the SmPC and section 2 of the PL to align the wording for the excipient sodium with the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017 Rev. 1*).
IA/0055	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	12/04/2022	n/a		
IAIN/0054	B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	10/02/2022	13/05/2022	SmPC, Labelling and PL	
IAIN/0053/G	This was an application for a group of variations. 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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	18/11/2021	13/05/2022	Annex II and PL	

IA/0052	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	21/09/2021	n/a		
IB/0051/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	07/07/2021	13/05/2022	SmPC, Labelling and PL	The Product Information was updated to add the additional pack size of two pre-filled syringes for each of the four strengths.
IAIN/0050	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	26/05/2021	n/a		
IAIN/0049	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	09/04/2021	13/05/2022	Annex II and PL	

	responsible for importation and/or batch release - Not including batch control/testing				
T/0048	Transfer of Marketing Authorisation	22/12/2020	25/02/2021	SmPC, Labelling and PL	
IB/0047	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/01/2021	n/a		
IAIN/0046	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	22/10/2020	n/a		
IB/0045	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	16/10/2020	25/02/2021	SmPC	
PSUSA/10118 /201909	Periodic Safety Update EU Single assessment - midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)	28/05/2020	27/07/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10118/201909.
IA/0044/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	22/06/2020	n/a		

	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				
IAIN/0042/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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.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	30/10/2019	n/a		
IB/0041/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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)	20/10/2019	27/07/2020	SmPC and Labelling	

IA/0039	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	03/08/2018	n/a		
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/07/2018	12/02/2019	Labelling	
IB/0037	B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue	24/05/2018	n/a		
IAIN/0036	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	02/02/2018	12/02/2019	Annex II and PL	
PSUSA/10118 /201609	Periodic Safety Update EU Single assessment - midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)	06/04/2017	n/a		PRAC Recommendation - maintenance
R/0032	Renewal of the marketing authorisation.	01/04/2016	26/05/2016	SmPC, Annex II, Labelling and PL	
IA/0033	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	02/05/2016	n/a		

PSUSA/10118 /201509	Periodic Safety Update EU Single assessment - midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)	17/03/2016	n/a		PRAC Recommendation - maintenance
IG/0603/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	03/12/2015	26/05/2016	SmPC, Annex II, Labelling and PL	
IG/0621	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	16/10/2015	n/a		
IA/0028	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	09/10/2015	n/a		
IA/0027	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	16/07/2015	n/a		
PSUSA/10118 /201409	Periodic Safety Update EU Single assessment - midazolam (oromucosal solution, treatment of prolonged, acute, convulsive seizures)	12/03/2015	n/a		PRAC Recommendation - maintenance

IB/0025/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites	29/10/2014	n/a		
IA/0024	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	26/09/2014	n/a		
IAIN/0023	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	02/07/2014	n/a		
PSUV/0012	Periodic Safety Update	10/04/2014	n/a		PRAC Recommendation - maintenance
IB/0020	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	28/03/2014	n/a		
IB/0021/G	This was an application for a group of variations. B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete	26/03/2014	n/a		

	parameter) B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation				
IB/0019	Update of section 6.6 of the SmPC to include information on how to administer Buccolam as already introduced in the Package Leaflet. In addition several editorial corrections including an update of the entire PI in accordance with QRD template version 9 have also been introduced. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/03/2014	05/03/2015	SmPC, Annex II, Labelling and PL	
IA/0022	A.7 - Administrative change - Deletion of manufacturing sites	27/02/2014	05/03/2015	Annex II and PL	
IAIN/0018	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	17/02/2014	n/a		
IAIN/0016/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations,	17/02/2014	n/a		

	and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system				
IA/0017	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/02/2014	n/a		
IB/0015	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	11/02/2014	n/a		
IB/0014	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	31/01/2014	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/01/2014	05/03/2015	Labelling and PL	The MAH applied for the introduction of a wrap-around tube label with improved visual images and a multi-strength Package Leaflet with the introduction of colour to differentiate between the strengths for optimum clarity. The labelling and PL have been updated accordingly.
IA/0013	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	19/12/2013	n/a		
IB/0008	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	07/11/2013	n/a		
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	06/11/2013	n/a		

	site				
IAIN/0009	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/10/2013	n/a		
IA/0007/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new or updated 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 or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	14/08/2013	n/a		
IA/0006	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	17/06/2013	n/a		
IAIN/0005/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the	02/05/2013	n/a		

	major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
IAIN/0004/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	13/12/2012	18/12/2013	SmPC, Annex II and PL	
IAIN/0003/G	This was an application for a group of variations. C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	22/08/2012	n/a		
IB/0002	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished	16/08/2012	n/a		

	product - Tightening of in-process limits				
IB/0001	B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	16/12/2011	n/a		