



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Vipidia

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/0035	Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information following positive opinion of procedure P46/013 and confirmation of full compliance of PIP EMEA-000496-PIP01-08-M08 (PIP decision: P/0257/2020) based on reports from study studies SYR-322_104 and SYR-	25/05/2023		SmPC and PL	Please refer to Scientific Discussion 'Vipidia H/C/002182/II/0035' A summary of paediatric studies agreed as part of the PIP is included in the SmPC. Use of Vipidia in the paediatric population is not recommended. For more information, please refer to the Summary of

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).



	322_309. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				Product Characteristics.
WS/2397/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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	26/01/2023	n/a		
IG/1566	A.7 - Administrative change - Deletion of manufacturing sites	10/10/2022	n/a		

WS/2327	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	15/09/2022	n/a		
N/0032	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/09/2022		PL	
WS/2191	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of a consolidated RMP version 11.1 for Vipidia, Vipdomet and Incresync in order to: - Update the RMPs for Alogliptin, Alogliptin/Pioglitazone fixed dose combination (FDC) and Alogliptin/Metformin fixed dose combination (FDC) to consolidate within a single RMP as committed within the PSUR procedure (PSUSA/00010061/202104). - Following review of cumulative safety data, removal of a number of safety concerns is done based on GVP Module V, Risk Management Systems (revision 2) guidelines. - Remove the target follow up Questionnaires of	10/06/2022	n/a		n/a

	Severe Hypersensitivity and skin reactions, Pancreatitis, Hepatic events and follow up gastrointestinal events and infections from Alogliptin and Alo/Met RMPs. - Reflect the removal of the inverted black triangle as agreed as part of the alogliptin renewal procedure (EMA/H/C/002178/R/0023) for Alogliptin and the FDC Alogliptin/Metformin. The black triangle was already removed from the FDC Alogliptin/Pioglitazone RMP as part of the Type II variation (EMA/H/C/002178/II/0029). 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				
IG/1486/G	This was an application for a group of variations. B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold 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	13/04/2022	n/a		
N/0028	Minor change in labelling or package leaflet not	09/11/2021	04/04/2022	PL	

	connected with the SPC (Art. 61.3 Notification)				
PSUSA/10061/202104	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	28/10/2021	n/a		PRAC Recommendation - maintenance
WS/1967/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation A.1 - Administrative change - Change in the name and/or address of the MAH	18/03/2021	04/04/2022	SmPC, Annex II, Labelling and PL	
WS/1966	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	14/01/2021	n/a		
PSUSA/10061/202004	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	12/11/2020	07/01/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10061/202004.
PSUSA/10061/201904	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	31/10/2019	n/a		PRAC Recommendation - maintenance

IG/1071/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.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.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold	28/03/2019	n/a		
PSUSA/10061 /201804	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	31/10/2018	n/a		PRAC Recommendation - maintenance
R/0019	Renewal of the marketing authorisation.	22/03/2018	24/05/2018	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 Vipidia in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10061 /201704	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	26/10/2017	n/a		PRAC Recommendation - maintenance
WS/1235/G	This was an application for a group of variations following a worksharing procedure according to	14/09/2017	n/a		

	Article 20 of Commission Regulation (EC) No 1234/2008. 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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
IB/0018	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	02/08/2017	n/a		
PSUSA/10061 /201604	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	27/10/2016	n/a		PRAC Recommendation - maintenance
IG/0734/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.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	13/10/2016	n/a		

	manufacturer 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				
WS/0940	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/04/2016	n/a		
IG/0652	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	22/01/2016	n/a		
PSUSA/10061 /201504	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	06/11/2015	n/a		PRAC Recommendation - maintenance
PSUSA/10061 /201410	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	10/04/2015	n/a		PRAC Recommendation - maintenance
PSUV/0007	Periodic Safety Update	20/11/2014	15/01/2015	SmPC and PL	Please refer to Vipidia PSUV/07 EPAR: Scientific conclusions

					and grounds recommending the variation to the terms of the marketing authorisation
IAIN/0009/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	21/11/2014	10/12/2015	SmPC, Labelling and PL	
IAIN/0008/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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	21/11/2014	15/01/2015	SmPC, Labelling and PL	
WS/0520	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	24/07/2014	15/01/2015	SmPC	

II/0001	The MAH proposed the update of sections 4.4, 4.8, and 5.1 of the SmPC and in order to reflect the results of study 402, a phase 3b, randomised, double-blind, placebo-controlled, event-driven study, designed to demonstrate that no excess risk of a major adverse cardiovascular event (MACE) exists following treatment with alogliptin compared with placebo when added to standard of care in adults with type II diabetes mellitus (T2DM) and acute coronary syndrome (ACS). The MAH took this opportunity to propose consequential amendments to the RMP and to update its structure according to the new European Union (EU) template for RMPs. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	24/07/2014	15/01/2015	SmPC	Results from study 402, a phase 3b, randomised, double-blind, placebo-controlled, event-driven study, which was designed to demonstrate that no excess risk of a major adverse cardiovascular event (MACE) exists following treatment with alogliptin compared with placebo when added to standard of care in adults with type II diabetes mellitus (T2DM) and acute coronary syndrome (ACS), are included in the SmPC. The primary endpoint of the study was achieved, demonstrating non-inferiority of alogliptin compared with placebo for the primary MACE composite. Therefore, in general, alogliptin was not associated with an increased risk of cardiovascular disease.
PSUV/0004	Periodic Safety Update	12/06/2014	n/a		PRAC Recommendation - maintenance
IB/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/05/2014	n/a		
II/0005	Update of section 4.4 of the SmPC in order to update the safety information on acute pancreatitis. The Package Leaflet is updated accordingly. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/04/2014	15/01/2015	SmPC and PL	The scope of this variation was to update section 4.4 of the SmPC to update the safety information on acute pancreatitis following recommendations of an Art 5(3) procedure on GLP-1-based therapies and pancreatic safety. The Package Leaflet is updated accordingly. The benefit/risk balance of Vipidia remains unchanged.

IG/0401	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	11/02/2014	n/a		
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