Incresync

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/10061 /201804	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	31/10/2018	n/a		PRAC Recommendation - maintenance
R/0023	Renewal of the marketing authorisation.	22/03/2018	25/05/2018	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

[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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					with unlimited validity.
IB/0022	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	08/01/2018	n/a		
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 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	14/09/2017	n/a		
IB/0021/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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.e - Change in test procedure for AS or starting	24/08/2017	n/a		

	material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0018/G	This was an application for a group of variations. 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 C.I.3.z - 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 - Other variation	11/01/2017	20/12/2017	SmPC, Annex II and PL	
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 manufacturer	13/10/2016	n/a		

	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				
IB/0015	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		
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
IA/0011	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/06/2015	n/a		

PSUSA/10061 /201410	Periodic Safety Update EU Single assessment - alogliptin, alogliptin / metformin, alogliptin / pioglitazone	10/04/2015	n/a		PRAC Recommendation - maintenance
PSUV/0008	Periodic Safety Update	20/11/2014	15/01/2015	SmPC and PL	Please refer to Incresync PSUV/08 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IAIN/0009	A.1 - Administrative change - Change in the name and/or address of the MAH	07/11/2014	15/01/2015	SmPC, Labelling and PL	
WS/0519	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. The WSA 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 amendments to the RMP in order to reflect results from study 402 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	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.

	data				
II/0002	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 305, a phase 3, randomised, double-blind, active-controlled, 2-year study, designed to assess the efficacy and safety of alogliptin in combination with metformin compared with glipizide in combination with metformin in adults with T2DM. The Package leaflet has been updated accordingly. The MAH took this opportunity to propose consequential amendments to the RMP. 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 and PL	Results from study 305, a phase 3, randomised, double-blind, active-controlled, 2-year study, designed to assess the efficacy and safety of alogliptin in combination with metformin compared with glipizide in combination with metformin in adults with T2DM, are included in the SmPC. Treatment with alogliptin as add on to metformin therapy showed similar results after two years of treatment to glipizide in combination with metformin treatment. The dose of glipizide used in this trial was relatively low. Furthermore, alogliptin therapy was associated with less hypoglycaemic periods compared to glipizide treatment and the weight of the alogliptin group reduced slightly as the weight of the glipizide group increased slightly. There were no specific safety issues in this trial.
PSUV/0005	Periodic Safety Update	12/06/2014	n/a		PRAC Recommendation - maintenance
IB/0007	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/05/2014	n/a		
II/0006	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 Incresync 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	11/02/2014	n/a		

	location				