



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Steglujan

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
WS/2729	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC for Steglatro, Steglujan and Segluromet in order to add 'rash' to	05/09/2024		SmPC and PL	

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).



	the list of adverse drug reactions (ADRs) related to ertugliflozin with frequency not known, based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10784 /202312	Periodic Safety Update EU Single assessment - ertugliflozin / metformin, ertugliflozin / sitagliptin, ertugliflozin	05/09/2024	n/a		PRAC Recommendation - maintenance
IB/0025/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.e.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supportive data 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.c.1.f - Change in the specification parameters and/or limits of an excipient - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or	18/09/2023	12/01/2024	SmPC and PL	

	quality issue B.II.c.1.f - Change in the specification parameters and/or limits of an excipient - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue				
WS/2537	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	31/08/2023	n/a		
IG/1640	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)	28/08/2023	n/a		
IG/1613	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)	19/06/2023	n/a		
IG/1623	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 -	16/06/2023	12/01/2024	Annex II and PL	

	Not including batch control/testing				
IG/1606/G	This was an application for a group of variations. 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 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	11/05/2023	n/a		
WS/2390	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.e.2 - Introduction of a post approval change management protocol related to the AS	30/03/2023	n/a		
IAIN/0020/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	15/12/2022	12/01/2024	SmPC, Annex II and PL	

	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 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				
R/0018	Renewal of the marketing authorisation.	15/09/2022	05/12/2022	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 Steglujan in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10784 /202112	Periodic Safety Update EU Single assessment - ertugliflozin / metformin, ertugliflozin / sitagliptin, ertugliflozin	01/09/2022	n/a		PRAC Recommendation - maintenance
II/0015	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/09/2021	18/11/2021	SmPC and PL	
IG/1426	A.7 - Administrative change - Deletion of manufacturing sites	03/08/2021	n/a		
WS/1825	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	23/07/2020	16/11/2021	SmPC and PL	

	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
PSUSA/10784 /201912	Periodic Safety Update EU Single assessment - ertugliflozin / metformin, ertugliflozin / sitagliptin, ertugliflozin	09/07/2020	n/a		PRAC Recommendation - maintenance
IB/0013	B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue	06/04/2020	n/a		
IG/1211	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	27/02/2020	n/a		
PSUSA/10681 /201906	Periodic Safety Update EU Single assessment - ertugliflozin / sitagliptin	16/01/2020	n/a		PRAC Recommendation - maintenance
IG/1157	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/11/2019	12/05/2020	SmPC, Annex II, Labelling and PL	
PSUSA/10681 /201812	Periodic Safety Update EU Single assessment - ertugliflozin / sitagliptin	11/07/2019	n/a		PRAC Recommendation - maintenance
WS/1590	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	23/05/2019	12/05/2020	SmPC and PL	

	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
PSUSA/10681/201806	Periodic Safety Update EU Single assessment - ertugliflozin / sitagliptin	31/01/2019	02/04/2019		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10681/201806.
WS/1488	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of the final CSR for Study P007/1017 - a Phase 3, randomized, double-blind, placebo-controlled, 26-week multicenter study with a 78-week extension to evaluate the efficacy and safety of ertugliflozin in subjects with type 2 Diabetes Mellitus and inadequate glycaemic control on metformin monotherapy - together with the final summarized data of all adjudicated confirmed fractures from the broad pool and pooled 2-year safety data from the 7 completed Phase 3 studies, including both 2-year studies P007/1017 and P002/1013. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/02/2019	n/a		No changes to the product information are warranted at present. The RMP will be updated at the next opportunity. The benefit/risk ration for Steglatro, Steglujan and Segluromet is unchanged.
T/0004	Transfer of Marketing Authorisation	12/07/2018	23/08/2018	SmPC, Labelling and PL	

IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/06/2018	23/08/2018	SmPC and PL	
IA/0002	B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised	29/05/2018	n/a		
IB/0001/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	26/04/2018	23/08/2018	SmPC, Labelling and PL	