Segluromet

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
IA/0025	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	29/07/2024	n/a		
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-	28/08/2023	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter)				
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/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		
II/0017	To include significant changes to sections 4.4 and 4.8 of the SmPC and section 4 of the Package Leaflet for the medicinal product Segluromet, containing the active substances Ertugliflozin L-pyroglutamic acid and Metformin hydrochloride, regarding the risk for	14/04/2023	27/03/2024	SmPC and PL	

	vitamin B12 deficiency. The topic was assessed as part of mutual recognition procedures (FR/H/0181/001-3) for the mono-component containing metformin product (Glucophage). The current proposed update of the product information for ertugliflozin/metformin combination product (Segluromet) is the same as for the mono-component product containing metformin. In addition, the MAH proposed minor editorial changes to the PI. The proposed update of the PI for the medicinal product Segluromet, containing the active substances Ertugliflozin L-pyroglutamic acid and Metformin hydrochloride. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0018/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.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.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological	04/01/2023	n/a		

	product) of a specification parameter wit its corresponding test method as a result of a safety or quality issue				
R/0015	Renewal of the marketing authorisation.	15/09/2022	09/11/2022	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 Segluromet in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0016	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)	19/10/2022	n/a		
PSUSA/10784 /202112	Periodic Safety Update EU Single assessment - ertugliflozin / metformin, ertugliflozin / sitagliptin, ertugliflozin	01/09/2022	n/a		PRAC Recommendation - maintenance
IA/0013/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/11/2021	n/a		
WS/1953	This was an application for a variation following a	16/09/2021	25/10/2021	SmPC and PL	Please refer to Scientific Discussion Steglatro and

	worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC of Steglatro and Segluromet in order to modify the indication, update posology recommendations and include efficacy and safety information based on final results from the VERTIS CV study (protocol 8835-004/B1521021) listed as a category 3 study in the RMP. This is a multi-centre, multi-national, randomised, double-blind, placebo-controlled study to evaluate the effect of ertugliflozin on cardiovascular risk in adult patients with type 2 diabetes and established atherosclerotic cardiovascular disease. The Package Leaflet is updated accordingly. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				Segluromet EMEA/H/C/WS1953
WS/1825	This was an application for a variation 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	23/07/2020	24/06/2021	SmPC and PL	
PSUSA/10784 /201912	Periodic Safety Update EU Single assessment - ertugliflozin / metformin, ertugliflozin / sitagliptin, ertugliflozin	09/07/2020	n/a		PRAC Recommendation - maintenance

IB/0010	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		
PSUSA/10680 /201906	Periodic Safety Update EU Single assessment - ertugliflozin / metformin	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/10680 /201812	Periodic Safety Update EU Single assessment - ertugliflozin / metformin	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. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/05/2019	12/05/2020	SmPC and PL	
PSUSA/10680 /201806	Periodic Safety Update EU Single assessment - ertugliflozin / metformin	31/01/2019	28/03/2019	SmPC and PL	Refer to Segluromet PSUSA/10680/201806 EPAR: Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation.
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	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.

	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				
T/0002	Transfer of Marketing Authorisation	12/07/2018	26/07/2018	SmPC, Labelling and PL	
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 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	26/04/2018	26/07/2018	SmPC, Labelling and PL	

	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				