Roteas

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/2409	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	12/10/2023	20/11/2023	SmPC, Labelling and PL	Following the review of paediatric data it was concluded that edoxaban is not recommended for use in children and adolescents from birth to 18 years of age with confirmed VTE (PE and/or DVT) event as the efficacy has not been established. Available data in VTE patients are described in sections 4.8, 5.1 and 5.2. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10387/202210	Periodic Safety Update EU Single assessment - edoxaban	25/05/2023	09/08/2023	SmPC, Labelling and	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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).

				PL	PSUSA/10387/202210.
WS/2510	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.c.1.z - Change in immediate packaging of the AS - Other variation	13/07/2023	n/a		
WS/2483	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	08/06/2023	n/a		
WS/2444	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	26/04/2023	n/a		
IG/1610	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	20/04/2023	n/a		

WS/2400	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.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	19/01/2023	n/a		
WS/2379/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 B.I.a.3.z - Change in batch size (including batch size ranges) of AS or intermediate - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	10/11/2022	n/a		
IG/1569	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	01/11/2022	n/a		
PSUSA/10387/202110	Periodic Safety Update EU Single assessment - edoxaban	10/06/2022	n/a		PRAC Recommendation - maintenance

WS/2190	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	22/04/2022	n/a		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Roteas in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IG/1484/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/03/2022	n/a		
WS/2078	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	24/02/2022	n/a		
R/0021	Renewal of the marketing authorisation.	14/10/2021	09/12/2021	SmPC and PL	
IG/1454/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an	05/11/2021	n/a		

	approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10387/202010	Periodic Safety Update EU Single assessment - edoxaban	10/06/2021	n/a		PRAC Recommendation - maintenance
IG/1364	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	06/05/2021	n/a		
WS/1895/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.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	26/11/2020	24/06/2021	SmPC, Labelling and PL	
WS/1922	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	26/11/2020	24/06/2021	SmPC, Labelling and PL	

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
WS/1760	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/11/2020	n/a		
WS/1880	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.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	10/09/2020	n/a		
WS/1756	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	25/06/2020	24/06/2021	SmPC, Annex II and PL	
PSUSA/10387/201910	Periodic Safety Update EU Single assessment - edoxaban	14/05/2020	n/a		PRAC Recommendation - maintenance

T/0013	Transfer of Marketing Authorisation	29/11/2019	18/12/2019	SmPC, Labelling and PL	
IAIN/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/06/2019	25/07/2019	SmPC, Labelling and PL	
PSUSA/10387/201810	Periodic Safety Update EU Single assessment - edoxaban	16/05/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10387/201804	Periodic Safety Update EU Single assessment - edoxaban	31/10/2018	n/a		PRAC Recommendation - maintenance
IG/0990/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.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)	30/10/2018	n/a		
IAIN/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/08/2018	25/07/2019	SmPC and PL	
PSUSA/10387/201710	Periodic Safety Update EU Single assessment - edoxaban	31/05/2018	26/07/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/10387/201710.
II/0003	Update of sections 4.2 and 5.1 of the SmPC in line with changes already introduce to Lixiana (EMEA/H/C/002629/II/0012) in order to add information deriving from clinical data for the use of edoxaban as anticoagulant therapy for patients with non-valvular atrial fibrillation undergoing cardioversion. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update section 4.8 of the SmPC as per the requirement of the finalised PSUSA/00010387/201610 procedure to include headache, abdominal pain and dizziness with a common frequency as new adverse drug reactions. The MAH also took the opportunity to bring the PI in line with the latest QRD template version 10.0 and to introduce some editorial changes and minor corrections. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	30/11/2017	26/07/2018	SmPC, Labelling and PL	Roteas can be initiated or continued in patients who may require cardioversion. For transoesophageal echocardiogram (TEE) guided cardioversion in patients not previously treated with anticoagulants, Roteas treatment should be started at least 2 hours before cardioversion to ensure adequate anticoagulation. Cardioversion should be performed no later than 12 hours after the dose of Roteas on the day of the procedure. For all patients undergoing cardioversion: Confirmation should be sought prior to cardioversion that the patient has taken Roteas as prescribed. Decisions on initiation and duration of treatment should follow established guidelines for anticoagulant treatment in patients undergoing cardioversion.
PSUSA/10387/201704	Periodic Safety Update EU Single assessment - edoxaban	30/11/2017	n/a		PRAC Recommendation - maintenance
WS/1230	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/10/2017	n/a		