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
R/0021	Renewal of tthe markeing authorisation.	14/10/2021	09/12/2021	SmPC and PL	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.

[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).

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 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	05/11/2021	n/a		
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. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/11/2020	24/06/2021	SmPC, Labelling and PL	
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.	25/06/2020	24/06/2021	SmPC, Annex II and PL	

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
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	30/10/2018	n/a		

	an obsolete parameter)				
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		