



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Riluzole Zentiva

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/2645/202112	Periodic Safety Update EU Single assessment - riluzole	15/09/2022	15/11/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/2645/202112.
IAIN/0031	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer	23/07/2021	06/09/2021	Annex II 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).



	responsible for batch release				
IA/0030	A.7 - Administrative change - Deletion of manufacturing sites	03/06/2021	n/a		
II/0027	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	26/11/2020	n/a		
IA/0028	A.7 - Administrative change - Deletion of manufacturing sites	09/09/2020	06/09/2021	Annex II and PL	
IA/0029/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	04/09/2020	n/a		
PSUSA/2645/201912	Periodic Safety Update EU Single assessment - riluzole	09/07/2020	n/a		PRAC Recommendation - maintenance
IB/0025	B.II.b.4.b - Change in the batch size (including batch	18/02/2020	n/a		

	size ranges) of the finished product - Downscaling down to 10-fold				
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/09/2018	06/09/2021	PL	
PSUSA/2645/201712	Periodic Safety Update EU Single assessment - riluzole	12/07/2018	n/a		PRAC Recommendation - maintenance
T/0023	Transfer of Marketing Authorisation	17/04/2018	08/05/2018	SmPC, Labelling and PL	
R/0021	Renewal of the marketing authorisation.	10/11/2016	09/01/2017	SmPC, Annex II, Labelling and PL	Based on on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Riluzole Zentiva in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/2645/201512	Periodic Safety Update EU Single assessment - riluzole	02/09/2016	n/a		PRAC Recommendation - maintenance
N/0020	Update of the package leaflet with revised contact details of the local representatives for Hungary, Italy and Lithuania. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/03/2016	09/01/2017	PL	
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/11/2015	09/01/2017	PL	

IAIN/0017	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 - Not including batch control/testing	28/07/2015	n/a		
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/07/2015	09/01/2017	PL	
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/11/2014	09/01/2017	PL	
PSUSA/2645/ 201312	Periodic Safety Update EU Single assessment - riluzole	11/09/2014	n/a		PRAC Recommendation - maintenance
IA/0014	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/08/2014	n/a		
IAIN/0013	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	05/08/2014	n/a		
IG/0454	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	17/07/2014	n/a		
N/0010	Minor change in labelling or package leaflet not	27/03/2014	11/07/2014	PL	

	connected with the SPC (Art. 61.3 Notification)				
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/12/2013	11/07/2014	SmPC, Annex II, Labelling and PL	
IA/0008/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/11/2013	n/a		
IAIN/0007/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 - Not including batch control/testing	12/09/2013	11/07/2014	Annex II and PL	
IG/0314	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	08/07/2013	n/a		
IB/0005/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters	04/07/2013	n/a		

	and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation				
IB/0004/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 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	03/07/2013	11/07/2014	SmPC, Annex II, Labelling and PL	
IB/0003	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	15/01/2013	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/10/2012	11/07/2014	PL	

IG/0192	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	06/07/2012	n/a		
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