Rizmoic

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
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/06/2024		PL	
IAIN/0024/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release	11/01/2024	n/a		

[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).

	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 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				
R/0023	Renewal of the marketing authorisation.	14/09/2023	03/11/2023	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 Rizmoic in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Amendments to annexes I, II and III were made to implement changes in line with the SmPC guideline and the current QRD template. Removal of black triangle sign from the annexes following five years of authorisation.
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/06/2023	03/11/2023	PL	
IAIN/0021/G	This was an application for a group of variations. 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 A.1 - Administrative change - Change in the name	08/03/2023	03/11/2023	SmPC, Annex II, Labelling and PL	

	and/or address of the MAH				
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/12/2022	03/11/2023	PL	
IG/1553	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	06/12/2022	n/a		
PSUSA/10753 /202203	Periodic Safety Update EU Single assessment - naldemedine	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0017	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/07/2022	n/a		
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/12/2021	03/11/2023	PL	
PSUSA/10753 /202103	Periodic Safety Update EU Single assessment - naldemedine	28/10/2021	n/a		PRAC Recommendation - maintenance
IAIN/0014/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/05/2021	n/a		

PSUSA/10753 /202009	Periodic Safety Update EU Single assessment - naldemedine	09/04/2021	n/a		PRAC Recommendation - maintenance
IG/1359	A.7 - Administrative change - Deletion of manufacturing sites	10/03/2021	n/a		
IA/0012	A.7 - Administrative change - Deletion of manufacturing sites	15/12/2020	01/02/2021	SmPC, Annex II, Labelling and PL	
PSUSA/10753 /202003	Periodic Safety Update EU Single assessment - naldemedine	29/10/2020	n/a		PRAC Recommendation - maintenance
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	13/08/2020	n/a		
PSUSA/10753 /201909	Periodic Safety Update EU Single assessment - naldemedine	17/04/2020	n/a		PRAC Recommendation - maintenance
IAIN/0008/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.b - Replacement or addition of a	23/03/2020	01/02/2021	Annex II and PL	

	manufacturing site for the FP - Primary 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 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 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				
IAIN/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/03/2020	n/a		
II/0005/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation 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.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	05/03/2020	n/a		

	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms				
II/0004	Update of section 5.2 of the SmPC based on the final report from non-clinical study S-297995-PF-360-N submitted as agreed in the letter of recommendation to CHMP: In-vitro data determining whether naldemedine inhibits in a time dependent manner the OATP1B1, OATP1B3, OAT1 and OAT3 transporters. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	30/01/2020	01/02/2021	SmPC	Results of in vitro study S-297995-PF-360-N did not demonstrate significant inhibitory effect of S-297995 monotosylate on the in vitro transporter activity of OATP1B1, OATP1B3, OAT1, or OAT3 in the tested concentrations (max concentration=10 µmol/L). There¬fore, Naldemedine administered in the attended amount of 200 µg is not expected to affect the pharmacokinetics of co-administered drugs that are substrates of these transporters.
PSUSA/10753 /201903	Periodic Safety Update EU Single assessment - naldemedine	17/10/2019	16/12/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10753/201903.
IA/0003	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	12/07/2019	n/a		
IB/0001/G	This was an application for a group of variations.	13/06/2019	16/12/2019	SmPC, Labelling and	

	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within 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			PL	