



## Mayzent

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
PSUSA/10818 /202203	Periodic Safety Update EU Single assessment - siponimod	10/11/2022	12/01/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10818/202203.
PSUSA/10818 /202109	Periodic Safety Update EU Single assessment - siponimod	19/05/2022	18/07/2022	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



					PSUSA/10818/202109.
IG/1521	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/06/2022	n/a		
IA/0016/G	<p>This was an application for a group of variations.</p> <p>B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p> <p>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</p> <p>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</p>	01/06/2022	n/a		
IB/0015/G	<p>This was an application for a group of variations.</p> <p>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</p>	08/03/2022	n/a		

	<p>the AS -replacement or addition of a site where batch control/testing takes place</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p> <p>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</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p>				
X/0007	Annex I_2.(c) Change or addition of a new strength/potency	16/12/2021	16/02/2022	SmPC, Labelling and PL	
II/0011/G	<p>This was an application for a group of variations.</p> <p>Update of section 4.5 of the SmPC to clarify the CYP2C9/CYP3A4 inhibitors/inducers information.</p> <p>Update of section 5.2 to add information regarding CYP2C9 genotypes less frequent alleles.</p> <p>Update of sections 4.4 and 4.5 of the SmPC to add information in case of administration of non-live attenuated vaccines, based on the vaccination study A2130.</p> <p>C.I.z - Changes (Safety/Efficacy) of Human and</p>	11/11/2021	16/02/2022	SmPC	For more information, please refer to the Summary of Product Characteristics.

	Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
PSUSA/10818 /202103	Periodic Safety Update EU Single assessment - siponimod	28/10/2021	n/a		PRAC Recommendation - maintenance
IAIN/0013/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 B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information 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)	06/10/2021	16/02/2022	Annex II and PL	
IA/0012	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	06/08/2021	n/a		
IB/0009/G	This was an application for a group of variations.	13/07/2021	n/a		

	<p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p> <p>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</p>				
PSUSA/10818 /202009	Periodic Safety Update EU Single assessment - siponimod	09/04/2021	n/a		PRAC Recommendation - maintenance
IA/0006/G	<p>This was an application for a group of variations.</p> <p>B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits</p> <p>B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits</p> <p>B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method</p>	22/01/2021	n/a		

PSUSA/10818 /202003	Periodic Safety Update EU Single assessment - siponimod	12/11/2020	07/01/2021	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10818/202003.
IAIN/0004	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	21/08/2020	07/01/2021	Annex II and PL	
IB/0002/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	02/04/2020	07/01/2021	SmPC, Labelling and PL	
IAIN/0001	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	17/02/2020	07/01/2021	SmPC, Labelling and PL	