



LEDAGA

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
IB/0026	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	25/02/2021		SmPC, Labelling and PL	
IB/0025/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other	11/12/2020	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).



	variation B.I.z - Quality change - Active substance - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
PSUSA/10587/202002	Periodic Safety Update EU Single assessment - chlormethine	01/10/2020	n/a		PRAC Recommendation - maintenance
IA/0023/G	This was an application for a group of variations. 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.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	06/08/2020	n/a		
IB/0022	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure	21/07/2020	n/a		

	(including replacement or addition)				
IB/0020/G	<p>This was an application for a group of variations.</p> <p>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)</p> <p>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</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p>	17/07/2020	n/a		
PSUSA/10587/201908	Periodic Safety Update EU Single assessment - chlormethine	12/03/2020	n/a		PRAC Recommendation - maintenance
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/10/2019	28/02/2020	Labelling	
IAIN/0018	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/10/2019	n/a		
IB/0016	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	17/09/2019	n/a		
PSUSA/10587/201902	Periodic Safety Update EU Single assessment - chlormethine	05/09/2019	n/a		PRAC Recommendation - maintenance

IB/0015	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	23/08/2019	n/a		
IAIN/0012	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	10/05/2019	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	28/02/2020	PL	
IB/0009/G	This was an application for a group of variations. 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.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue 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	03/04/2019	n/a		

	<p>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.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.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.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>				
IAIN/0010/G	<p>This was an application for a group of variations.</p> <p>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)</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>A.7 - Administrative change - Deletion of</p>	15/03/2019	28/02/2020	Annex II, Labelling and PL	

	<p>manufacturing sites</p> <p>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</p>				
PSUSA/10587/201808	Periodic Safety Update EU Single assessment - chlormethine	14/03/2019	n/a		PRAC Recommendation - maintenance
T/0008	Transfer of Marketing Authorisation	22/11/2018	18/12/2018	SmPC, Labelling and PL	
PSUSA/10587/201802	Periodic Safety Update EU Single assessment - chlormethine	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10587/201708	Periodic Safety Update EU Single assessment - chlormethine	08/03/2018	n/a		PRAC Recommendation - maintenance
IG/0839	<p>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</p>	20/11/2017	28/05/2018	SmPC, Annex II and PL	
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.z - Quality change - Finished product - Other variation</p> <p>B.II.z - Quality change - Finished product - Other variation</p>	15/09/2017	n/a		

IA/0001	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	28/06/2017	28/05/2018	SmPC and PL	
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