Myclausen

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/10550 /202305	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	25/01/2024	27/03/2024	SmPC	Please refer to CellCept, Myclausen, Mycophenolate mofetil teva, Myfenax EMEA/H/C/PSUSA/00010550/202305 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0057	B.II.b.3.a - Change in the manufacturing process of	06/07/2023	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).

	the finished or intermediate product - Minor change in the manufacturing process				
IB/0056	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	29/03/2023	n/a		
IB/0055/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	22/12/2022	n/a		
IB/0054/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by	01/08/2022	30/08/2023	SmPC and PL	Section 5.1 of the SmPC has been updated based on a literature review on mycophenolate mechanism of action. Section 5.2 of the SmPC has been updated to add new information to the Distribution and Elimination subsections. Sections 4.5 and 5.2 of the SmPC have been updated to amend the existing information on patients taking oral contraceptives.

	the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				Section 2 of the Package Leaflet has been updated to align the wording of the text with the SmPC section 4.4.
PSUSA/10550 /202105	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	16/12/2021	16/02/2022	PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10550/202105.
IA/0053	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	24/08/2021	n/a		

	relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
IB/0051	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	16/07/2021	16/02/2022	SmPC and PL	
PSUSA/10550 /202005	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	10/12/2020	18/02/2021	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10550/202005.
IA/0050/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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	23/12/2020	n/a		

	control/testing takes place				
IA/0048	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)	29/01/2020	n/a		
PSUSA/10550 /201905	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	28/11/2019	n/a		PRAC Recommendation - maintenance
IB/0046/G	This was an application for a group of variations. 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) 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	17/04/2019	n/a		
IA/0045/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting	19/03/2019	n/a		

	material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				

	B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
PSUSA/10550 /201805	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	29/11/2018	n/a		PRAC Recommendation - maintenance
IA/0044	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	20/11/2018	n/a		
PSUSA/10550 /201705	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	14/12/2017	05/03/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10550/201705.
IA/0042/G	This was an application for a group of variations. B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient	26/10/2017	n/a		

	- Minor changes to an approved test procedure B.II.c.2.b - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is already authorised B.II.c.2.b - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test procedure is already authorised				
IA/0040/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	14/06/2017	n/a		
IA/0039	A.7 - Administrative change - Deletion of manufacturing sites	11/05/2017	05/03/2018	Annex II and PL	
N/0038	Update of the package leaflet with revised contact details of the local representative for Czech Republic. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/10/2016	05/03/2018	PL	
IA/0037	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	22/07/2016	n/a		

IAIN/0036	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/06/2016	n/a		
IAIN/0035	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	18/03/2016	12/08/2016	Annex II and PL	
IB/0033	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	08/02/2016	12/08/2016	SmPC, Annex II and PL	
IAIN/0034	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	22/12/2015	n/a		
IAIN/0032	A.1 - Administrative change - Change in the name and/or address of the MAH	14/12/2015	12/08/2016	SmPC, Labelling and PL	
IB/0031/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	18/08/2015	12/08/2016	SmPC, Annex II and PL	

	new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0030	A.1 - Administrative change - Change in the name and/or address of the MAH	12/08/2015	12/08/2016	SmPC, Labelling and PL	
IA/0029	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)	16/07/2015	n/a		
R/0023	Renewal of the marketing authorisation.	26/03/2015	27/05/2015	SmPC, Annex II, Labelling	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing

				and PL	authorisation was granted, the CHMP considered that the benefit-risk balance of Myclausen in the approved indications remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0028	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	29/01/2015	27/05/2015	SmPC and PL	
IA/0027	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	23/12/2014	n/a		
IA/0025/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	23/12/2014	n/a		
IA/0026	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	22/12/2014	n/a		

	relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
IA/0024	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	22/12/2014	n/a		
IA/0022/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	24/10/2014	27/05/2015	Annex II and PL	
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/04/2014	27/10/2014	PL	
IB/0020	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	30/10/2013	27/10/2014	SmPC, Annex II, Labelling and PL	

IB/0019	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	21/10/2013	27/10/2014	SmPC	
IAIN/0018	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/09/2013	n/a		
IB/0017	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	13/09/2012	29/10/2012	SmPC and PL	Update of Section 4.5 of the SmPC to include information regarding the interaction with proton pump inhibitors following the outcome of PSUR 18 assessment (covering period: 01.05.08-30.04.11) of the Reference Product. The Package Leaflet has been updated accordingly. The MAH also took the opportunity to introduce minor linguistic amendments in the Danish, Finish, Norwegian and Swedish PI.
IAIN/0016/G	This was an application for a group of variations. 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	10/09/2012	n/a		
IB/0015	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	16/12/2011	28/06/2012	SmPC	
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/10/2011	n/a	PL	

X/0003	To register a new pharmaceutical form and strength 250 mg hard capsules Annex I_2.(d) Change or addition of a new pharmaceutical form	21/07/2011	16/09/2011	SmPC, Labelling and PL	
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/06/2011	n/a	PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/04/2011	n/a	PL	
IA/0010	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	15/03/2011	n/a		
IA/0009	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	15/03/2011	n/a		
IA/0006	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	15/03/2011	n/a	Annex II and PL	
IA/0005	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	15/03/2011	n/a	Annex II and PL	
IA/0004	B.III.1.a.3 - Submission of a new or updated Ph. Eur.	15/03/2011	n/a		

	Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)				
IA/0011	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	11/03/2011	n/a		
IA/0008	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/03/2011	n/a		
IA/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/03/2011	n/a		
IB/0001	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	19/01/2011	n/a	PL	Changes to the PIL section 2. BEFORE YOU TAKE MYCLAUSEN - Take special care with Myclausen and Pregnancy and breast-feeding recommended by the CHMP following the assessment of the originator product.
IA/0002	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/01/2011	n/a		