Cystadrops

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
IAIN/0033/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	10/12/2024		SmPC, Annex II, Labelling 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).

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
IA/0031	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	01/10/2024	n/a		
PSUSA/10574 /202401	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	05/09/2024	n/a		PRAC Recommendation - maintenance
IA/0028	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)	06/12/2023	n/a		
IB/0027	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	09/11/2023	n/a		
IA/0025/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	16/01/2023	n/a		

	procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IA/0024	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	22/06/2022	n/a		
II/0023	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	07/04/2022	n/a		
R/0022	Renewal of the marketing authorisation.	22/07/2021	15/09/2021	SmPC, Labelling and PL	
PSUSA/10574 /202101	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0020	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	15/10/2020	n/a		
IB/0019	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g.	23/09/2020	15/09/2021	SmPC, Annex II, Labelling	

	tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes			and PL	
PSUSA/10574 /202001	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	03/09/2020	n/a		PRAC Recommendation - maintenance
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/05/2020	15/09/2021	PL	
IA/0016	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/03/2020	n/a		
PSUSA/10574 /201901	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	05/09/2019	n/a		PRAC Recommendation - maintenance
IG/1085/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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)	16/05/2019	04/05/2020	SmPC, Annex II, Labelling and PL	

N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2019	04/05/2020	PL	
PSUSA/10574 /201807	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	14/02/2019	n/a		PRAC Recommendation - maintenance
IB/0012/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	15/01/2019	n/a		
IA/0011/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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	19/12/2018	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/11/2018	04/05/2020	PL	

PSUSA/10574 /201801	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	06/09/2018	n/a		PRAC Recommendation - maintenance
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/05/2018	04/05/2020	Labelling and PL	
IB/0006/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	08/03/2018	n/a		
PSUSA/10574 /201707	Periodic Safety Update EU Single assessment - mercaptamine (Indicated for the treatment of corneal cystine crystal deposit only)	08/02/2018	n/a		PRAC Recommendation - maintenance
IA/0003/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	11/09/2017	n/a		

	B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test				
IA/0002/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	10/08/2017	n/a		
IAIN/0001/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	16/02/2017	11/01/2018	Annex II and PL	