Idefirix

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/10870 /202408	Periodic Safety Update EU Single assessment - imlifidase	13/03/2025	n/a		PRAC Recommendation - maintenance
PSUSA/10870 /202402	Periodic Safety Update EU Single assessment - imlifidase	03/10/2024	n/a		PRAC Recommendation - maintenance
II/0024/G	This was an application for a group of variations. B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	12/09/2024	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).

	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS				
R/0020	Renewal of the marketing authorisation.	30/05/2024	24/07/2024		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Idefirix, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
II/0019	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/05/2024	24/07/2024	SmPC and Annex II	
PSUSA/10870 /202308	Periodic Safety Update EU Single assessment - imlifidase	11/04/2024	n/a		PRAC Recommendation - maintenance
IB/0021/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change	13/03/2024	n/a		

	to an approved stability protocol				
IAIN/0022	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	08/03/2024	24/07/2024	Annex II and PL	
PSUSA/10870 /202302	Periodic Safety Update EU Single assessment - imlifidase	28/09/2023	n/a		PRAC Recommendation - maintenance
R/0014	Renewal of the marketing authorisation.	25/05/2023	17/07/2023	SmPC	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Idefirix, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
II/0015	B.I.z - Quality change - Active substance - Other variation	04/05/2023	n/a		
II/0013	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	14/04/2023	n/a		
IB/0016	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	12/04/2023	n/a		
II/0010	B.I.b.2.d - Change in test procedure for AS or	23/03/2023	n/a		

	starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS				
PSUSA/10870 /202208	Periodic Safety Update EU Single assessment - imlifidase	16/03/2023	n/a		PRAC Recommendation - maintenance
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	13/01/2023	17/07/2023	Annex II and PL	
PSUSA/10870 /202202	Periodic Safety Update EU Single assessment - imlifidase	01/09/2022	n/a		PRAC Recommendation - maintenance
R/0007	Renewal of the marketing authorisation.	19/05/2022	15/07/2022	SmPC and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Idefirix, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0008	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	05/04/2022	n/a		

	material/intermediate				
PSUSA/10870 /202108	Periodic Safety Update EU Single assessment - imlifidase	10/03/2022	n/a		PRAC Recommendation - maintenance
IA/0006/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	15/12/2021	n/a		
PSUSA/10870 /202102	Periodic Safety Update EU Single assessment - imlifidase	30/09/2021	n/a		PRAC Recommendation - maintenance
R/0003	Renewal of the marketing authorisation.	20/05/2021	16/07/2021	SmPC, Annex II, Labelling and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Idefirix, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0002	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	29/10/2020	n/a		

IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	05/10/2020	16/07/2021	SmPC and PL	