



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EXPAREL liposomal

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/10889 /202310	Periodic Safety Update EU Single assessment - bupivacaine (liposomal formulations)	16/05/2024	n/a		PRAC Recommendation - maintenance
II/0018	B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range	21/03/2024	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).



PSUSA/10889 /202304	Periodic Safety Update EU Single assessment - bupivacaine (liposomal formulations)	30/11/2023	n/a		PRAC Recommendation - maintenance
IAIN/0017	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/11/2023	n/a		
IA/0016	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/10/2023	n/a		
IB/0014	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	16/08/2023	n/a		
IB/0013/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)	06/06/2023	n/a		
PSUSA/10889 /202210	Periodic Safety Update EU Single assessment - bupivacaine (liposomal formulations)	12/05/2023	n/a		PRAC Recommendation - maintenance
II/0011/G	This was an application for a group of variations. B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	04/05/2023	n/a		

	B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product				
PSUSA/10889 /202204	Periodic Safety Update EU Single assessment - bupivacaine (liposomal formulations)	01/12/2022	n/a		PRAC Recommendation - maintenance
II/0005	Extension of indication to include treatment of children aged 6 and older as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds for EXPAREL liposomal; as a consequence, sections 4.1,4.2, 4.4, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	15/09/2022	07/11/2022	SmPC and PL	Please refer to Scientific Discussion EXPAREL liposomal EMEA/H/C/004586/II/0005.
PSUSA/10889 /202110	Periodic Safety Update EU Single assessment - bupivacaine (liposomal formulations)	05/05/2022	n/a		PRAC Recommendation - maintenance
IB/0009/G	This was an application for a group of variations. B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of	19/04/2022	n/a		

	specification limits B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier				
IB/0006	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	07/12/2021	n/a		
IA/0007/G	This was an application for a group of variations. B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	22/11/2021	n/a		

A.z - Administrative change - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
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IB/0004/G	This was an application for a group of variations. B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	29/10/2021	n/a		
PSUSA/10889 /202104	Periodic Safety Update EU Single assessment - bupivacaine (liposomal formulations)	28/10/2021	n/a		PRAC Recommendation - maintenance
IB/0002/G	This was an application for a group of variations. B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	13/07/2021	n/a		