EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ZYNRELEF

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/10880 /202303	Periodic Safety Update EU Single assessment - bupivacaine/meloxicam	26/10/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10880 /202209	Periodic Safety Update EU Single assessment - bupivacaine/meloxicam	26/04/2023	23/06/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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).

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					PSUSA/10880/202209.
II/0011	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/04/2023	23/06/2023	SmPC and PL	
II/0009/G	This was an application for a group of variations. B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation 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 - Minor changes to an approved test procedure B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	12/01/2023	n/a		
PSUSA/10880 /202203	Periodic Safety Update EU Single assessment - bupivacaine/meloxicam	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0006/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	16/06/2022	23/06/2023	SmPC	

	(supported by real time data)				
IA/0007/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 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	03/06/2022	n/a		
PSUSA/10880 /202109	Periodic Safety Update EU Single assessment - bupivacaine/meloxicam	07/04/2022	n/a		PRAC Recommendation - maintenance
IB/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	03/03/2022	n/a		
IB/0002/G	This was an application for a group of variations. B.II.c.z - Change in control of excipients in the	12/01/2022	n/a		

	Finished Product - Other variation B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure				
IB/0004	B.II.e.z - Change in container closure system of the Finished Product - Other variation	05/01/2022	n/a		
PSUSA/10880 /202103	Periodic Safety Update EU Single assessment - bupivacaine/meloxicam	28/10/2021	n/a		PRAC Recommendation - maintenance