

Rexxolide

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued / amended on	Product Information affected ²	Summary ³
IB/0004	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	10/09/2021		SPC and PL	The Agency accepted the variation to update section 4.5 "Special precautions for use" of the SPC and section 12 "Special warnings" of the PL following assessment of the same change for the reference product Draxxin following PSUR assessment.
IB/0003	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	01/07/2021		SPC and PL	The Agency accepted the variation to update the product information for Rexxolide in order to align with the product information of the reference product (Draxxin).
IB/0002/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.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an	18/05/2021	n/a		n/a

¹ Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.

² SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

³ Since October 2019 summary information is no longer published for variations that do not impact upon the product information

	ASMF 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.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF				
IB/0001/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/03/2021	n/a		n/a