Repaglinide Krka

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
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/12/2022		PL	
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/12/2021		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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

IA/0017	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	02/07/2021	n/a		
IB/0016/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/10/2020	19/10/2021	SmPC, Annex II, Labelling and PL	
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/10/2017	19/10/2021	Labelling and PL	
IA/0014	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	26/10/2017	n/a		
IA/0013	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	28/07/2017	n/a		
IA/0012/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	09/02/2017	n/a		

	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
IB/0011/G	This was an application for a group of variations. 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 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	28/06/2016	16/02/2017	SmPC, Annex II and PL	
IA/0010	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	08/06/2016	n/a		
IAIN/0009	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	23/03/2016	16/02/2017	Annex II and PL	
R/0007	Renewal of the marketing authorisation.	26/06/2014	22/08/2014		This is a renewal of the Marketing Authorisation for a generic product.

					During the renewal period no significant information has arisen that alters the overall assessment of the benefit/risk balance of the product. The CHMP recommends that the renewal be granted with unlimited validity.
IAIN/0008	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	30/04/2014	n/a		
IAIN/0006/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	18/12/2013	22/08/2014	Annex II and PL	
IA/0005/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	08/10/2013	n/a		
IAIN/0004	B.III.1.a.3 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur.	08/03/2013	n/a		

	Monograph - New certificate from a new manufacturer (replacement or addition)				
IB/0003/G	This was an application for a group of variations. Updated section 4.5 of the SmPC in order to include a new drug-drug interaction with deferasirox. Section 2 of the Package Leaflet has been updated accordingly. The Product Information has also been updated in line with the latest QRD template (version 8). The MAH took this opportunity to harmonise the text with the originator to include a new indication, which is already approved for the reference product. All changes have been made in order to harmonise the text with the originator. 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 are submitted by the MAH 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 are submitted by the MAH	26/07/2012	n/a	SmPC, Annex II, Labelling and PL	
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	05/07/2012	n/a	SmPC, Annex II and PL	

IB/0001	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	22/05/2012	n/a		