EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

IKERVIS

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/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/02/2023		PL	
IB/0034	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	31/01/2023	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).

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

IAIN/0033	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/12/2022	n/a		
PSUSA/10362 /202203	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0032	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	04/10/2022	n/a		
IA/0031/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 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 A.7 - Administrative change - Deletion of manufacturing sites	20/09/2022	n/a		
IB/0029	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	24/01/2022	28/11/2022	SmPC, Labelling and PL	
II/0026/G	This was an application for a group of variations.	16/12/2021	28/11/2022	SmPC,	

	B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products			Labelling and PL	
PSUSA/10362 /202103	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	28/10/2021	n/a		PRAC Recommendation - maintenance
IB/0028	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	14/07/2021	n/a		
PSUSA/10362 /202009	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	09/04/2021	n/a		PRAC Recommendation - maintenance
IG/1315	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	08/03/2021	n/a		
PSUSA/10362	Periodic Safety Update EU Single assessment -	01/10/2020	n/a		PRAC Recommendation - maintenance

/202003	ciclosporin (topical use)				
IB/0023	B.III.1.z - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Other variation	21/07/2020	n/a		
PSUSA/10362 /201909	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	17/04/2020	n/a		PRAC Recommendation - maintenance
IG/1227/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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	15/04/2020	26/03/2021	SmPC, Annex II and PL	
R/0017	Renewal of the marketing authorisation.	13/02/2020	09/03/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of IKERVIS in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0018	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	20/02/2020	n/a		
IG/1163/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	21/11/2019	n/a		

	manufacturing sites B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation 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				
PSUSA/10362 /201903	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	03/10/2019	n/a		PRAC Recommendation - maintenance
WS/1490	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	29/05/2019	04/07/2019	SmPC, Labelling and PL	
PSUSA/10362 /201809	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	11/04/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10362 /201803	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	04/10/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10362 /201709	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	12/04/2018	n/a		PRAC Recommendation - maintenance

IB/0010	B.II.e.z - Change in container closure system of the Finished Product - Other variation	07/12/2017	n/a		
PSUSA/10362 /201703	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	28/09/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10362 /201609	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	06/04/2017	n/a		PRAC Recommendation - maintenance
IAIN/0008/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	09/01/2017	29/06/2017	Annex II and PL	
PSUSA/10362 /201603	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	29/09/2016	n/a		PRAC Recommendation - maintenance
II/0005	Update of sections 5.1 - Pharmacodynamic properties of the SmPC in order to include an efficacy and safety summary results regarding Post-SANSIKA study (Study NVG12D122) – "Multicenter, open label, interventional, prospective, non-randomized, one cohort extension study to assess the sustainability of the effect of NOVA22007 1 mg/ml in Severe Dry Eye Disease (DED) following	21/07/2016	29/06/2017	SmPC, Labelling and PL	

	discontinuation of treatment in improved patients” In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes in the SmPC, Annex IIIA and Annex IIIB C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10362 /201509	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	14/04/2016	n/a		PRAC Recommendation - maintenance
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/12/2015	29/06/2017	PL	
IAIN/0002	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	21/10/2015	n/a		
T/0001	Marketing Authorisation Transfer from Santen S.A.S to Santen Oy. Transfer of Marketing Authorisation	13/05/2015	11/06/2015	SmPC, Labelling and PL	