Verkazia

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
R/0021	Renewal of the marketing authorisation.	26/01/2023	31/03/2023	SmPC, Annex II, Labelling and PL	
IAIN/0022	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/02/2023	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).

PSUSA/10362 /202203	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0020	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/0019/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.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 A.7 - Administrative change - Deletion of manufacturing sites	14/09/2022	n/a		
IB/0017	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	24/01/2022	21/09/2022	SmPC, Labelling and PL	
PSUSA/10362 /202103	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	28/10/2021	n/a		PRAC Recommendation - maintenance
II/0013/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the	28/10/2021	21/09/2022	SmPC, Labelling and PL	The SmPC has been updated as follows: The Product Information has been revised to include the new PFMD presentation; All sections of the SmPC are

	finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range 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				identical to the current approved version for single-dose containers with the exception of sections: "4.2 Posology and method of administration",: in paragraph "Method of administration" the text "For single use only. Each single-dose container is sufficient to treat both eyes. Any unused emulsion should be discarded immediately" has been deleted; the text "Patients should be informed of the correct handling of the multidose container. For instructions for use, see section 6.6" has been added; "6.3 Shelf life": 2 years. After first opening of the bottle: 4 weeks. Store below 25°C; "6.4 Special precautions for storage": Do not freeze. Store below 25°C. For storage conditions after first opening of the medicinal product, see section 6.3; "6.5 Nature and contents of container": Verkazia is supplied sterile in a white low density polyethylene bottle (9 mL fill in a 11 mL container) and white nozzle with tamper evident system. Carton containing 1 bottle. "6.6 Special precautions for disposal": instructions for use have been added for the new multidose container The Labelling and PL as well as Annex A have been updated accordingly.
IB/0016	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	19/07/2021	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 /202003	Periodic Safety Update EU Single assessment - ciclosporin (topical use)	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0011	B.III.1.z - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Other variation	07/07/2020	n/a		
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/06/2020	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	31/03/2021	SmPC, Annex II and PL	

IG/1163/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of 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	21/11/2019	n/a		
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
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/03/2019	04/07/2019	PL	

IB/0003	B.II.e.z - Change in container closure system of the Finished Product - Other variation	24/01/2019	n/a		