# Siklos

## Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
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| Article 61(3) / | - Notification acc. Article 61(3) - Accepted | 28/04/2026 | | 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).

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| EMA/N/0000341113 | Update of the package leaflet with revised contact details of local representatives. | | | | |
| Article 61(3) / EMA/N/0000326005 | - Notification acc. Article 61(3) - Accepted<br><br>Update of the package leaflet with revised contact details of local representatives. | 11/02/2026 | 13/04/2026 | PL | |
| PSUR / EMA/PSUR/0000296554 | In view of available data on limbal stem cell deficiency risk from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between hydroxycarbamide and limbal stem cell deficiency is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing hydroxycarbamide should be amended accordingly. | 29/01/2026 | 13/04/2026 | SmPC and PL | Variation |
| Article 61(3) / EMA/N/0000313374 | - Notification acc. Article 61(3) - Accepted<br><br>Update of package leaflet with revised contact details of local representatives. | 24/11/2025 | 13/04/2026 | PL | |
| Article 61(3) / EMA/N/0000302461 | - Notification acc. Article 61(3) - Accepted<br><br>Update of the package leaflet with revised | 30/09/2025 | 13/04/2026 | PL | |

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| | contact details of local representatives. | | | | |
| Variation type IB / EMA/VR/0000247430 | B.II.e.1 Change in immediate packaging of the finished product - B.II.e.1.z Other changes - Accepted | 26/02/2025 | | | |