# EXDENSUR

## 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 |
|---|---|---|---|---|---|
| Variation type IB / | This was an application for a group of | 08/05/2026 | | SmPC | |

[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/VR/0000340523 | variations.<br><br>Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.a) Minor change to an approved analytical procedure - Accepted<br>Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.a) Minor change to an approved analytical procedure - Accepted<br>Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted<br>Q.II Finished product - Q.II.z Other variation - Accepted | | | | |
| Variation type IB / EMA/VR/0000340521 | This was an application for a group of variations.<br><br>Q.I.a) Manufacture - Q.I.a.z Other variation - Accepted<br>Q.I.c.3 Change in analytical procedure for the immediate packaging of the active substance - Q.I.c.3.z Other variation - Accepted<br>Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.a) Minor change to an | 07/05/2026 | | | |

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| | analytical procedure for the active substance - Accepted<br>Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.a) Minor change to an analytical procedure for the active substance - Accepted<br>Q.I.e.8 Changes to an approved product lifecycle management document (PLCM) related to the active substance - Q.I.e.8.b) Minor changes to an approved PLCM - Accepted<br>Q.I.e.8 Changes to an approved product lifecycle management document (PLCM) related to the active substance - Q.I.e.8.b) Minor changes to an approved PLCM - Accepted<br>Q.I.e.8 Changes to an approved product lifecycle management document (PLCM) related to the active substance - Q.I.e.8.b) Minor changes to an approved PLCM - Accepted<br>Q.I.e.8 Changes to an approved product lifecycle management document (PLCM) related to the active substance - Q.I.e.8.b) Minor changes to an approved PLCM - Accepted<br>Q.I.e.8 Changes to an approved product lifecycle management document (PLCM) related to the active substance - Q.I.e.8.b) | | | | |

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| | Minor changes to an approved PLCM - Accepted | | | | |