



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Awikli

### 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/<br>Notification<br><sup>1</sup> issued on | Commission<br>Decision<br>Issued <sup>2</sup> /<br>amended on | Product<br>Information<br>affected <sup>3</sup> | Summary |
|---------------------|--------------------------------------|----------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------|---------|
| Variation type IB / | B.I.a.2 Changes in the manufacturing | 09/10/2025                                         | N/A                                                           |                                                 |         |

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



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|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----|--------------------------|--|
| EMA/VR/0000296481                        | process of the active substance - B.I.a.2.a<br>Minor change in the manufacturing process<br>of the active substance - Accepted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |            |     |                          |  |
| Variation type IA /<br>EMA/VR/0000303372 | B.II.d.2 Change in test procedure for the<br>finished product - B.II.d.2.a Minor changes<br>to an approved test procedure - Accepted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 07/10/2025 | N/A |                          |  |
| Variation type II /<br>EMA/VR/0000268356 | <p>C.I HUMAN AND VETERINARY MEDICINAL<br/>PRODUCTS - C.I.4 Change(s) in the<br/>Summary of Product Characteristics,<br/>Labelling or Package Leaflet due to new<br/>quality, preclinical, clinical or<br/>pharmacovigilance data - Accepted</p> <p>Update of sections 4.4, and 5.1 of the SmPC<br/>in order to update information related to<br/>medication errors based on post-marketing<br/>data and data from clinical trials and to<br/>introduce minor editorial changes; the<br/>Package Leaflet (PL) is updated accordingly.<br/>The RMP version 2.1 has also been<br/>submitted in order to add new important<br/>identified risk of "Medication errors with<br/>accidental overdose, due to erroneous<br/>transfer of dosing habits from other once-<br/>weekly injectable antidiabetic medicines".<br/>Update of Annex IID to add a list of<br/>instructions to be included in the educational<br/>guide to counter dosing errors. In addition,<br/>"ankle swelling" was reworded to "swelling</p> | 02/10/2025 |     | SmPC, Annex<br>II and PL |  |

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|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----|--|--|
|                                          | around ankles" in the PL.                                                                                                                                                                                                                                                                                           |            |     |  |  |
| Variation type IB /<br>EMA/VR/0000294854 | B.I.d.1.a Re-test period/storage period -<br>B.I.d.1.a.4 Extension or introduction of a re-<br>test period/storage period supported by real<br>time data - Accepted                                                                                                                                                 | 25/09/2025 | N/A |  |  |
| Variation type II /<br>EMA/VR/0000269577 | B.I.b.1 Change in the specification<br>parameters and/or limits of an active<br>substance, starting material / intermediate /<br>reagent used in the manufacturing process<br>of the active substance - B.I.b.1.f Change<br>outside the approved specifications limits<br>range for the active substance - Accepted | 24/07/2025 | N/A |  |  |
| Variation type II /<br>EMA/VR/0000269515 | B.II.g) Design Space and post approval<br>change management protocol - B.II.g.2<br>Introduction of a post approval change<br>management protocol related to the finished<br>product - Accepted                                                                                                                      | 24/07/2025 | N/A |  |  |
| Variation type IA /<br>EMA/VR/0000267525 | B.II.e.2 Change in the specification<br>parameters and/or limits of the immediate<br>packaging of the finished product - B.II.e.2.c<br>Deletion of a non-significant specification<br>parameter (e.g. deletion of an obsolete<br>parameter) - Accepted<br><br>B.II.e.2 Change in the specification                  | 21/05/2025 | N/A |  |  |

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|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                          | parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted                                                                                                                               |            |     |      |                                                                                                                                                                                                                                                  |
| Variation type IA /<br>EMA/VR/0000267870 | B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted<br><br>B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted | 20/05/2025 | N/A |      |                                                                                                                                                                                                                                                  |
| Variation type IB /<br>EMA/VR/0000247985 | B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted                                                                                                          | 04/03/2025 |     | SmPC |                                                                                                                                                                                                                                                  |
| PSUR / EMA/PSUR/0000248499               | - -                                                                                                                                                                                                                                                                                                                              |            |     |      | Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing Insulin remains unchanged and therefore recommends the maintenance of the marketing authorisation(s). |