EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



# Zoledronic acid Actavis

## 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 |
|---|---|---|---|---|---|
| IG/1612 | A.1 - Administrative change - Change in the name and/or address of the MAH | 31/05/2023 | | SmPC, Labelling and PL | |
| N/0025 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 05/11/2021 | | 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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| IA/0024 | B.II.f.1.e - Stability of FP - Change to an approved stability protocol | 09/07/2021 | n/a | | |
| IB/0023 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 09/09/2020 | 22/09/2021 | SmPC, Annex II, Labelling and PL | |
| N/0022 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 06/01/2020 | 22/09/2021 | PL | |
| IA/0021 | A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient | 08/08/2019 | n/a | | |
| IA/0020 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 07/05/2019 | n/a | | |
| N/0019 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 05/10/2018 | 22/09/2021 | PL | |
| IB/0018 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO | 03/10/2017 | 28/09/2018 | SmPC and PL | |

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| | new additional data is required to be submitted by the MAH | | | | |
| R/0017 | Renewal of the marketing authorisation. | 13/10/2016 | 08/12/2016 | SmPC, Labelling and PL | |
| IB/0016 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 07/07/2016 | 08/12/2016 | SmPC, Labelling and PL | |
| IA/0015 | B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits | 16/05/2016 | n/a | | |
| IA/0014 | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 14/01/2016 | n/a | | |
| IA/0012/G | This was an application for a group of variations.<br><br>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 16/12/2015 | n/a | | |

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| IAIN/0013 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 14/12/2015 | 08/12/2016 | SmPC and PL | |
| IB/0011 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 09/10/2015 | 10/12/2015 | SmPC, Annex II and PL | |
| 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 | 17/06/2015 | n/a | | |
| IAIN/0010 | C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location | 12/06/2015 | n/a | | |
| IA/0007 | A.7 - Administrative change - Deletion of manufacturing sites | 23/04/2015 | n/a | | |
| IB/0006 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 08/01/2015 | 10/12/2015 | SmPC and PL | |
| N/0005 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 13/08/2014 | 10/12/2015 | PL | |

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| IB/0004 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 15/01/2014 | 20/02/2014 | SmPC and PL | |
| IB/0003 | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) | 16/08/2013 | 20/02/2014 | SmPC | |
| IB/0002 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH | 16/07/2013 | 20/02/2014 | SmPC, Annex II and PL | |
| IB/0001 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH | 10/01/2013 | 20/02/2014 | SmPC and PL | |