



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zoledronic acid Teva

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
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/09/2021		PL	
IB/0026	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/05/2021	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).



IB/0027	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	19/04/2021	n/a		
IB/0025	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	18/09/2020	22/01/2021	SmPC, Annex II, Labelling and PL	
IB/0024	C.I.7.b - Deletion of - a strength	30/01/2020	22/01/2021		
IB/0023/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting</p>	05/09/2019	n/a		

material/intermediate/reagent - Tightening of specification limits

B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate

B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method

B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place

B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test

B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised

B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure

B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method

IA/0022	A.7 - Administrative change - Deletion of manufacturing sites	08/08/2019	09/12/2019	Annex II and PL	
IB/0021	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	17/12/2018	n/a		
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	27/02/2018	28/09/2018	Annex II and PL	
IB/0019	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	06/10/2017	28/09/2018	SmPC and PL	
R/0018	Renewal of the marketing authorisation.	23/03/2017	22/05/2017	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Zoledronic acid Teva in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0017	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	18/10/2016	n/a		
IB/0016	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	25/08/2016	22/05/2017	SmPC and PL	

IAIN/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/12/2015	11/02/2016	SmPC and PL	
IB/0014	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	20/10/2015	11/02/2016	SmPC, Annex II and PL	
IA/0013/G	<p>This was an application for a group of variations.</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its</p>	11/05/2015	n/a		

	<p>corresponding test method</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>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</p>				
IB/0012/G	<p>This was an application for a group of variations.</p> <p>Update of sections 4.4 and 4.5 of the SmPC to add information on additive effect of hypocalcaemia-causing medicinal products;</p> <p>Update of section 4.6 of the SmPC to add information for women of child-bearing potential;</p> <p>Update of section 4.8 of the SmPC to change frequency of uveitis (from "very rare" to "rare"); and</p> <p>Update of section 5.2 of the SmPC to revise the text on plasma protein binding.</p> <p>Furthermore. editorial changes are made to update some adverse reaction terms in section 4.8 of the SmPC according to MedDRA preferred terms. The</p>	19/02/2015	11/02/2016	SmPC and PL	

	<p>Package Leaflet is updated accordingly.</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>				
T/0011	Transfer of Marketing Authorisation	08/12/2014	19/12/2014	SmPC, Labelling and PL	

X/0008	To include a new pharmaceutical form Annex I_2.(d) Change or addition of a new pharmaceutical form	24/07/2014	01/10/2014	SmPC, Annex II, Labelling and PL	For further information, please refer to the Assessment Report Zoledronic acid-H-2439-X-08-AR-en.
IAIN/0010	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	30/04/2014	27/06/2014	Annex II and PL	
IB/0009	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	19/03/2014	27/06/2014	SmPC and PL	
IA/0007/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new	16/12/2013	n/a		

	<p>specification parameter to the specification with its corresponding test method</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.c.3.b - Change in test procedure for the immediate packaging of the AS - Other changes to a test procedure (including replacement or addition)</p>				
IAIN/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	16/07/2013	n/a		
IB/0005	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	15/07/2013	27/06/2014	SmPC, Annex II and PL	
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 are submitted by the MAH	17/01/2013	27/06/2014	SmPC and PL	
IB/0002/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation</p>	04/12/2012	n/a		

	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/10/2012	n/a		