



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ivabradine Zentiva

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
IB/0015	B.II.a.2.b - Change in the shape or dimensions of the pharmaceutical form - Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses	13/07/2023		SmPC and 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).



II/0014	B.I.z - Quality change - Active substance - Other variation	20/04/2023	n/a		
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/08/2022		PL	
IB/0012	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	31/05/2022	n/a		
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	07/02/2022	24/03/2023	SmPC, Labelling and PL	
IB/0010	B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	07/01/2022	n/a		
IA/0009	A.7 - Administrative change - Deletion of manufacturing sites	13/12/2021	n/a		
R/0008	Renewal of the marketing authorisation.	22/07/2021	29/09/2021	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 Ivabradine Zentiva in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

IB/0007	B.II.z - Quality change - Finished product - Other variation	12/11/2020	n/a		
IB/0006/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p>	06/02/2020	29/01/2021	Annex II and PL	

	<p>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</p> <p>B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.II.d.2.d - Change in test procedure for the finished</p>				
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	<p>product - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.d.2.e - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.</p> <p>B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation</p> <p>B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products</p>				
IB/0005/G	<p>This was an application for a group of variations.</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</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>	07/05/2019	n/a		
IG/1029	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	18/12/2018	n/a		
IA/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.2.a - Change in test procedure for an excipient</p>	15/05/2018	n/a		

	<ul style="list-style-type: none"> - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient <ul style="list-style-type: none"> - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient <ul style="list-style-type: none"> - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient <ul style="list-style-type: none"> - Minor changes to an approved test procedure 				
IB/0002	B.II.z - Quality change - Finished product - Other variation	28/09/2017	n/a		
IB/0001	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)	21/08/2017	13/08/2018	SmPC	