



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Pregabalin Zentiva k.s.

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IB/0022/G	This was an application for a group of variations.  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	17/11/2022		SmPC and PL	To update Section 4.4 and 4.8 of the SmPC to reflect new data on suicidal ideation following assessment of the same changes adopted for the reference product. Package Leaflet has been updated accordingly.  To update sections 4.4 and 4.8 of the SmPC, to implement

<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).



	<p>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>the wording related to the cases of abuse and dependence in patients without a history of substance disorder, following same assessment for Parent Product; Package Leaflet has been updated accordingly.</p> <p>Minor editorial changes in the following languages: BG, KR, CZ, ET, FR, EL, IT, LV, MT, NL, PL, SK, SL.</p>
IB/0021/G	<p>This was an application for a group of variations.</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.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation</p>	29/04/2022		SmPC and PL	<p>Section 4.4 of the SmPC was updated to include warning about Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) and Section 4.8 of the SmPC was updated to include "toxic epidermal necrolysis" with frequency "rare" in order to implement the signal recommendations on EMA/PRAC/13256/2022 (EPITT no 19723) adopted at the 10-13 January 2022 PRAC meeting. The PL has been updated accordingly.</p> <p>Sections 4.4 and 4.6 of the SmPC and Section 2 of the PL were updated with warning for women of childbearing potential/contraception.</p>
IB/0020	<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>	17/01/2022		SmPC and PL	
R/0019	Renewal of the marketing authorisation.	16/09/2021	22/11/2021	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of

					Pregabalin Zentiva k.s. in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
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 new additional data is required to be submitted by the MAH	27/05/2021	22/11/2021	SmPC	
IB/0017/G	<p>This was an application for a group of variations.</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>	22/01/2021	10/03/2021	SmPC, Labelling and PL	
IA/0016/G	<p>This was an application for a group of variations.</p> <p>B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)</p>	12/11/2020	n/a		

	<p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p>				
IB/0015	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	26/03/2020	10/03/2021	SmPC, Labelling and PL	
IAIN/0014/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p>	08/10/2019	n/a		
IB/0012	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	27/08/2019	n/a		

IB/0011/G	<p>This was an application for a group of variations.</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.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation</p>	27/08/2019	n/a		
IB/0013	<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>	22/08/2019	16/12/2019	SmPC, Annex II and PL	
IA/0010/G	<p>This was an application for a group of variations.</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)</p>	15/05/2019	n/a		
IB/0008	<p>B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the</p>	14/02/2019	n/a		

	relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer				
IAIN/0009/G	<p>This was an application for a group of variations.</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.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing</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>	11/01/2019	16/12/2019	Annex II and PL	
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		
IAIN/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/10/2018	n/a		
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process</p>	14/06/2018	n/a		

	test as a result of a safety or quality issue B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IAIN/0005/G	<p>This was an application for a group of variations.</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p>	18/05/2018	28/11/2018	SmPC, Labelling and PL	

	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IAIN/0004	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	18/05/2018	28/11/2018	SmPC, Labelling and PL	
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 is required to be submitted by the MAH	21/03/2018	28/11/2018	SmPC	
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 is required to be submitted by the MAH	20/12/2017	28/11/2018	SmPC and PL	