



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/412568/2020

BiResp Spiromax

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
PSUSA/10585 /201908	Periodic Safety Update EU Single assessment - budesonide / formoterol	30/04/2020	13/07/2020	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/10585/201908.
IA/0034	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	24/06/2020	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).



	relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
II/0030	<p>Updates of section 4.2 to add information on the use as reliever for allergen- and exercise-induced bronchoconstriction, section 4.4 to revise the general warning on complete withdrawal of inhaled corticosteroids; and section 6.6 to update the statement on special precautions for disposal and other handling following assessment of the same changes for the reference product Symbicort Turbohaler 160 mcg/4.5 mcg. The Package Leaflet (PL) and Labelling are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the PL and to introduce some minor editorial amendments in the PI for the following languages: FR, NO and PT.</p> <p>C.I.2.b - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Change(s) require to be further substantiated by new additional data to be submitted by the MAH</p>	30/01/2020	09/03/2020	SmPC and PL	In section 4.2 of the SmPC, information related to the use of BiResp Spiromax as reliever therapy for allergen- and exercise-induced bronchoconstriction was added to inform that preventative use of BiResp Spiromax should be discussed between physician and patient; the recommended use should take into consideration the frequency of need. In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. Section 4.4 of the SmPC is updated to inform healthcare professionals that the complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma. Section 6.6 of the SmPC is updated to reflect that any unused medicinal product or waste material should be disposed of in accordance with local requirements. The PL is updated accordingly.
IA/0032	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	31/01/2020	n/a		
IA/0029/G	This was an application for a group of variations.	28/06/2019	n/a		

	<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.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</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.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer</p>				
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/06/2019	09/03/2020	PL	
R/0027	Renewal of the marketing authorisation.	31/01/2019	08/04/2019	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 BiResp Spiromax in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0026	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	08/11/2018	n/a		
II/0024/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.b - Change in the manufacturing process of</p>	26/07/2018	n/a		

	<p>the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product</p> <p>B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes</p>				
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	25/06/2018	08/04/2019	SmPC	
IA/0023	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	08/03/2018	n/a		
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/11/2017	01/03/2018	PL	
IAIN/0020	C.I.3.a - 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 - Implementation of wording agreed by the competent authority	09/06/2017	01/03/2018	SmPC and PL	
IB/0018	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	19/04/2017	n/a		

IB/0019/G	<p>This was an application for a group of variations.</p> <p>B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information</p> <p>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation</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>	24/03/2017	01/03/2018	SmPC, Labelling and PL	
IA/0017	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	24/02/2017	n/a		
PSUSA/10202 /201604	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	01/12/2016	n/a		PRAC Recommendation - maintenance
IB/0015/G	<p>This was an application for a group of variations.</p> <p>B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information</p> <p>B.II.e.7.z. - Change in supplier of packaging components or devices (when mentioned in the</p>	17/10/2016	n/a		

	dossier) - Other variation				
IAIN/0016	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	07/10/2016	n/a		
A31/0006	Pursuant to Article 31 of Directive 2001/83/EC, the European Commission initiated a procedure on 27 April 2015 further to concerns over the risk of pneumonia in patients with chronic obstructive pulmonary disease when treated with inhaled corticosteroids containing medicinal products. The PRAC was requested to assess the impact thereof on the benefit-risk balance of inhaled corticosteroids containing medicinal products and to give its recommendation whether the marketing authorisation of these products should be maintained, varied, suspended or revoked.	28/04/2016	04/07/2016	SmPC and PL	Please refer to the assessment report: Inhaled corticosteroids containing products indicated in the treatment of chronic obstructive pulmonary disease- EMA/H/A-31/1415
IB/0013/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure	14/06/2016	n/a		

	(including replacement or addition)				
PSUSA/10202 /201510	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	13/05/2016	n/a		PRAC Recommendation - maintenance
IB/0012	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	22/04/2016	n/a		
PSUSA/10202 /201504	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	06/11/2015	n/a		PRAC Recommendation - maintenance
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/11/2015	04/07/2016	PL	
IB/0009/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	17/09/2015	04/07/2016	SmPC, Annex II, Labelling and PL	
IA/0007/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	24/07/2015	n/a		

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
PSUSA/10202 /201410	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	07/05/2015	n/a		PRAC Recommendation - maintenance
II/0001/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/12/2014	n/a		
IA/0003	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	27/08/2014	n/a		
IA/0002	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	18/08/2014	n/a		