Fortacin

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
R/0023	Renewal of the marketing authorisation.	26/07/2018	17/09/2018	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 Fortacin in the approved indication remains favourable, but recommended that one additional five-year renewal be required based on the following pharmacovigilance grounds: Limited safety information is available because of limited exposure, due to recent marketing and the limited

[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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					marketing of the medicinal product.
IA/0025	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	29/08/2018	n/a		
IA/0022	A.7 - Administrative change - Deletion of manufacturing sites	15/02/2018	17/09/2018	Annex II and PL	
IB/0020	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	02/02/2018	n/a		
IA/0021/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	24/01/2018	n/a		
PSUSA/10110 /201705	Periodic Safety Update EU Single assessment - lidocaine / prilocaine (centrally authorised product only)	30/11/2017	n/a		PRAC Recommendation - maintenance
T/0019	Transfer of Marketing Authorisation	11/10/2017	30/10/2017	SmPC, Labelling and PL	
IB/0017/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits	27/06/2017	n/a		

	applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
PSUSA/10110 /201611	Periodic Safety Update EU Single assessment - lidocaine / prilocaine (centrally authorised product only)	09/06/2017	n/a		PRAC Recommendation - maintenance
II/0015	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	23/03/2017	n/a		
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/01/2017	17/03/2017	Labelling	
PSUSA/10110 /201605	Periodic Safety Update EU Single assessment - lidocaine / prilocaine (centrally authorised product only)	01/12/2016	n/a		PRAC Recommendation - maintenance
N/0013	Update of the package leaflet to include the list of local representatives. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/08/2016	17/03/2017	PL	
PSUSA/10110 /201511	Periodic Safety Update EU Single assessment - lidocaine / prilocaine (centrally authorised product only)	09/06/2016	n/a		PRAC Recommendation - maintenance

IB/0011/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 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 B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products	17/05/2016	17/03/2017	SmPC, Annex II, Labelling and PL	
IAIN/0010/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	19/04/2016	17/03/2017	Annex II and PL	

	site 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 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 B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)				
PSUSA/10110 /201505	Periodic Safety Update EU Single assessment - lidocaine / prilocaine (centrally authorised product only)	03/12/2015	n/a		PRAC Recommendation - maintenance
PSUSA/10110 /201411	Periodic Safety Update EU Single assessment - lidocaine / prilocaine (centrally authorised product only)	11/06/2015	n/a		PRAC Recommendation - maintenance
IA/0007	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	27/03/2015	n/a		
IA/0006	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	27/03/2015	n/a		

IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/03/2015	n/a		
PSUV/0001	Periodic Safety Update	04/12/2014	n/a		PRAC Recommendation - maintenance
IAIN/0003	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	28/11/2014	n/a		
IAIN/0002/G	This was an application for a group of variations. A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	26/09/2014	15/10/2015	SmPC, Labelling and PL	