EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel Acino

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/0018/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 new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a	05/01/2016	28/01/2016	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).

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	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 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 C.I.2.z - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Other variation				
IB/0017	To update of section 4.8 of the SmPC to add 2 new undesirable effects: "Acutegeneralised exanthematous pustulosis" (AGEP) and "Gynaecomastia" in line with originator changes. The Package Leaflet has been updated accordingly. 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	28/05/2015	28/01/2016	SmPC and PL	
PSUSA/820/201311	Periodic Safety Update EU Single assessment - ACETYLSALICYLIC ACID; CLOPIDOGREL	10/07/2014	n/a		PRAC Recommendation - maintenance

IAIN/0016	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	27/06/2014	n/a		
IB/0015/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 new additional data is required to be submitted by the MAH 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	24/04/2014		SmPC and PL	
R/0012	Renewal of the marketing authorisation.	23/01/2014	21/03/2014	PL	The CHMP recommended renewal for an unlimited period of time.
IB/0013	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	26/11/2013	21/03/2014	SmPC	
IB/0011/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a	10/10/2013	21/03/2014	SmPC and PL	

	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 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				
IB/0010/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 new additional data are submitted by the MAH 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	13/08/2013	21/03/2014	SmPC, Annex II, Labelling and PL	
IAIN/0009	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	04/04/2012	n/a		
T/0008	Transfer of a marketing authorisation for Clopidogrel Acino 75 mg film-coated tablets	30/01/2012	06/03/2012	SmPC, Labelling and	

	Transfer of Marketing Authorisation			PL	
IB/0007	To update section 4.2 "Posology and method of administration" and 5.1 "Pharmacodynamic properties" of clopidogrel SPC to include new paediatric information available for clopidogrel. Minor linguistic changes have been introduced in the product information, to bring the product in line with the reference product. 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	22/07/2011	n/a	SmPC	
IB/0006	To update the Summary of Product Characteristics (SmPC) and Package Leaflet to update sections 4.2 "Posology and method of administration", 4.4 "Special warnings and precautions for use", 4.5 "Interaction with other medicinal products and other forms of interaction" and 5.2 "Pharmacokinetic properties" of clopidogrel/acetylsalicylic acid (ASA) SPC to include new information on the variability of response to clopidogrel due to either genetic variations of the CYP2C19 enzyme or concomitant use of drugs that inhibit the CYP2C19 enzyme such as proton pump inhibitor (PPI). In addition, section 4.8 has been amended with minor details on the CURE study. Additional changes have been added to the SmPC and Package Leaflet in order to bring it in line with the revised QRD template (version 7.3) In addition, the	29/04/2011	n/a	SmPC, Annex II and PL	To update the Summary of Product Characteristics (SmPC) and Package Leaflet to update sections 4.2 "Posology and method of administration", 4.4 "Special warnings and precautions for use", 4.5 "Interaction with other medicinal products and other forms of interaction" and 5.2 "Pharmacokinetic properties" of clopidogrel/acetylsalicylic acid (ASA) SPC to include new information on the variability of response to clopidogrel due to either genetic variations of the CYP2C19 enzyme or concomitant use of drugs that inhibit the CYP2C19 enzyme such as proton pump inhibitor (PPI). In addition, section 4.8 has been amended with minor details on the CURE study. Additional changes have been added to the SmPC and Package Leaflet in order to bring it in line with the revised QRD template (version 7.3) In addition, the deletion of DDPS number version and date was introduced in Annex IIB as requested by the EMA with the procedural

	deletion of DDPS number version and date was introduced in Annex IIB as requested by the EMA with the procedural announcement in October and November 2010. Minor linguistic changes have been introduced in the product information, to bring the product in line with the reference product. 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				announcement in October and November 2010. Minor linguistic changes have been introduced in the product information, to bring the product in line with the reference product.
A20/0004	Pursuant to Article 20 of Regulation (EC) No 726/2004 of 31 March 2004, the European Commission requested on 18 March 2010, the opinion of the CHMP on measures necessary to ensure the quality of the above mentioned medicinal product further to GMP deficiencies of the API manufacturing site Glochem Industries Ltd. (Unit II).	18/03/2010	16/09/2010		Please refer to the Assessment Report: Clopidogrel Acino-H-1166-A20-04-Assessment Report-Article 20
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 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	06/08/2010	n/a	SmPC, Labelling and PL	To include information on the clopidogrel metabolism pathway, the role of CYP2C19 genetic polumorphism on clopidogrel variability of response and the potential interaction between clopidogrel and CYP2C19 inhibitors including some proton pump inhibitors. The MAH also took the oportunity to make align to the originator products. Furthermore the list of local representatives was deleted from the Package Leaflet. Additionally, the marketing authorisation number and date were added.

	new additional data are submitted by the MAH				
II/0003	To register a revised version of the ASMF for clopidogrel besilate from the existing active substance manufacturer, introducing changes in the manufacturing process of the active substance. Quality changes	21/01/2010	02/02/2010		
II/0002	To introduce a new active substance manufacturer. Quality changes	21/01/2010	02/02/2010		
IA/0001	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site IA_07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	13/11/2009	n/a		