Cuprymina

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.	22/04/2022	21/06/2022	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Cuprymina in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. PL section 1 should be revised in line with the SPC section

[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).

					4.1, as follows (‘and authorised being added text): ‘Cuprymina is used for radiolabelling, a technique in which a substance is tagged (radiolabelled) with a radioactive compound. Cuprymina is used to label certain medicines that have been specially developed and authorised for use with the active substance copper (64Cu) chloride’.
PSUSA/10040 /201908	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	12/03/2020	n/a		PRAC Recommendation - maintenance
T/0022	Transfer of Marketing Authorisation	31/01/2020	28/02/2020	SmPC, Labelling and PL	
IB/0020	B.II.z - Quality change - Finished product - Other variation	13/11/2019	n/a		
IB/0019/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.II.z - Quality change - Finished product - Other variation	09/08/2019	n/a		
IA/0018	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/05/2019	n/a		
PSUSA/10040 /201808	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	14/03/2019	n/a		PRAC Recommendation - maintenance
IB/0016	B.II.e.6.z - Change in any part of the (primary)	30/04/2018	17/04/2019	SmPC,	

	packaging material not in contact with the finished product formulation - Other variation			Labelling and PL	
PSUSA/10040 /201708	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	08/03/2018	n/a		PRAC Recommendation - maintenance
R/0014	Renewal of the marketing authorisation.	18/05/2017	19/07/2017	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 Cuprymina in the approved indication remains favourable, but recommended that one additional five-year renewal be required based on the following pharmacovigilance grounds: The very limited exposure to Cuprymina (cumulative total sales of 152 vials in the EU) is considered to be grounds for requiring an additional five-year renewal. This would enable the generation of further data which would provide assurance that any risks for this product have been detected and adequately characterised in the post-marketing setting.
PSUSA/10040 /201608	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	09/03/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10040 /201602	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	02/09/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10040 /201508	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	17/03/2016	n/a		PRAC Recommendation - maintenance
IAIN/0011	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer	17/02/2016	16/03/2016	Annex II and	

	responsible for batch release			PL	
IAIN/0010/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient 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	17/02/2016	16/03/2016	SmPC, Labelling and PL	
IB/0008	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)	16/10/2015	16/03/2016	SmPC and Labelling	
PSUSA/10040 /201502	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	10/09/2015	n/a		PRAC Recommendation - maintenance
IB/0007/G	This was an application for a group of variations. B.I.a.1.a, B.II.b.1.a, B.II.b.1.f, B.II.b.2.c.2 - To add SPARKLE Srl, Contrada Calò, snc 73042 Casarano (LE) Italy as a site responsible the manufacture/QC of the intermediate/active substance, primary and secondary packaging, batch release including batch control/testing and manufacture of the finished	24/07/2015	16/03/2016	SmPC, Annex II, Labelling and PL	

	product. B.I.a.2.z, B.II.b.3.a - Minor change in the manufacturing process of the active substance and finished product due to different equipment used at the SPARKLE site. Furthermore, the MAH took the opportunity to update the fax no of the MAH in the SmPC and PIL. 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 B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products 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				
IAIN/0005/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH C.I.12 - Inclusion or deletion of black symbol and explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring	20/03/2015	16/03/2016	SmPC, Labelling and PL	
PSUSA/10040 /201408	Periodic Safety Update EU Single assessment - copper (64Cu) chloride	12/02/2015	n/a		PRAC Recommendation - maintenance
PSUV/0002	Periodic Safety Update	11/09/2014	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	09/07/2014	n/a		
PSUV/0001	Periodic Safety Update	13/06/2014	n/a		PRAC Recommendation - maintenance