Mirvaso

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/0034/G	This was an application for a group of variations. B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.e.1.a.2 - Change in immediate packaging of the	18/04/2023		SmPC, Labelling 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).

	finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms				
IAIN/0033/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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)	10/02/2023		Annex II and PL	
IA/0032	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	09/02/2022	n/a		
IB/0031	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	20/01/2022	n/a		
IB/0030	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/01/2022	23/01/2023	SmPC, Labelling and PL	

PSUSA/10093 /202102	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	30/09/2021	n/a		PRAC Recommendation - maintenance
IA/0028	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	07/01/2021	n/a		
PSUSA/10093 /202002	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	01/10/2020	n/a		PRAC Recommendation - maintenance
IA/0026	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	07/02/2020	n/a		
PSUSA/10093 /201902	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0025	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/07/2019	n/a		
IAIN/0023	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	25/04/2019	01/04/2020	Annex II and PL	
R/0021	Renewal of the marketing authorisation.	20/09/2018	22/11/2018	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

					Mirvaso in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10093 /201802	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	06/09/2018	n/a		PRAC Recommendation - maintenance
IB/0019/G	This was an application for a group of variations. B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	17/05/2018	n/a		
II/0017	Update of section 4.8 of the SmPC in order to update the frequency of the adverse drug reaction (ADR) rosacea from "uncommon" to "common" following a re-examination of the frequency of ADRs in pertinent studies. The package leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/04/2018	22/11/2018	SmPC and PL	
IA/0018	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	27/03/2018	n/a		

PSUSA/10093 /201708	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	08/03/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10093 /201702	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	01/09/2017	n/a		PRAC Recommendation - maintenance
IAIN/0015	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/06/2017	n/a		
PSUSA/10093 /201608	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	23/03/2017	24/05/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10093/201608.
IAIN/0013/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/03/2017	n/a		
IAIN/0012/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name	20/02/2017	24/05/2017	Annex II and PL	

	and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging 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				
IB/0011	C.I.3.z - 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 - Other variation	12/01/2017	24/05/2017	SmPC, Labelling and PL	
IB/0009	B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	16/12/2016	24/05/2017	SmPC, Labelling and PL	
PSUSA/10093 /201602	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	15/09/2016	11/11/2016	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10093/201602.
PSUSA/10093 /201508	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	17/03/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10093 /201502	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	24/09/2015	19/11/2015	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/10093/201502.
PSUSA/10093 /201408	Periodic Safety Update EU Single assessment - brimonidine (centrally authorised product only)	26/03/2015	02/06/2015	SmPC and PL	Please refer to Mirvaso PSUSA-10093-201408 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IAIN/0005	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	02/02/2015	n/a		
IAIN/0003/G	This was an application for a group of variations. B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/11/2014	n/a		
IB/0002/G	This was an application for a group of variations. B.II.e.1.b.1 - Change in immediate packaging of the	24/09/2014	02/06/2015	SmPC, Labelling and PL	

	finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms 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 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 B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier 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/0001/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/03/2014	n/a		