# Aerinaze

## 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 |
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| A31/0047 | Pursuant to Article 31 of Directive 2001/83/EC, the French National Competent Authority requested on 03 February 2023 the scientific opinion of the European Medicines Agency to further assess the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) associated with pseudoephedrine-containing medicinal products. The | 25/01/2024 | 27/03/2024 | SmPC and PL | Please refer to the assessment report: Aerinaze EMEA/H/A-31/1526/C/000772/0047 |

[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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| | Agency was requested to assess the impact thereof on the benefit-risk balance of pseudoephedrine containing-products and to give its recommendation whether the marketing authorisations of these products should be maintained, varied, suspended or revoked.<br>As the request results from the evaluation of data resulting from pharmacovigilance activities, the CHMP opinion should be adopted on the basis of a recommendation of the PRAC. | | | | |
| IAIN/0046 | A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | 07/12/2022 | | Annex II and PL | |
| PSUSA/963/202107 | Periodic Safety Update EU Single assessment - desloratadine / pseudoephedrine | 24/03/2022 | 30/05/2022 | SmPC and PL | Please refer to Aerinaze-EMEA/H/C/PSUSA/00000963/202107 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation |
| N/0044 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 27/10/2021 | 30/05/2022 | PL | |
| T/0043 | Transfer of Marketing Authorisation | 17/03/2021 | 13/04/2021 | SmPC, Labelling and PL | |
| N/0042 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 18/01/2021 | 13/04/2021 | PL | |
| N/0041 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 11/12/2020 | 13/04/2021 | PL | |

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| IA/0040/G | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 15/05/2020 | n/a | | |
| N/0039 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 03/02/2020 | 13/04/2021 | PL | |
| IG/1146 | 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 | 04/10/2019 | n/a | | |
| T/0037 | Transfer of Marketing Authorisation | 23/05/2018 | 15/06/2018 | SmPC, Labelling and PL | |
| IAIN/0036 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 08/12/2017 | | SmPC and PL | |
| IA/0035 | B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place | 20/11/2017 | n/a | | |

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| IAIN/0034 | 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 | 24/10/2017 | n/a | | |
| PSUSA/963/201607 | Periodic Safety Update EU Single assessment - desloratadine / pseudoephedrine | 23/03/2017 | 22/05/2017 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/963/201607. |
| II/0033 | Update of sections 4.4 and 4.8 of the SmPC to include information on acute generalised exanthematous pustulosis (AGEP) based on literature reports for pseudoephedrine. In addition, the MAH took the opportunity to correct minor typographical errors in the SmPC and Package Leaflet and to align the annexes with the revised QRD template v10.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 18/05/2017 | | SmPC, Labelling and PL | Severe skin reactions such as acute generalised exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema or many small pustules are observed, administration of Aerinaze should be discontinued and appropriate measures taken if needed. |
| IA/0031 | 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 | 17/10/2016 | n/a | | |
| IG/0704 | 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) | 01/08/2016 | n/a | | |

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| WS/0928 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 19/05/2016 | n/a | | |
| IA/0028 | 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 | 05/02/2015 | n/a | | |
| N/0027 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 02/10/2014 | 22/05/2017 | PL | |
| IG/0451 | 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 | 01/08/2014 | n/a | | |
| IG/0444 | 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 | 01/07/2014 | n/a | | |
| IG/0366 | 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 | 08/11/2013 | n/a | | |

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| | PSMF location | | | | |
| IB/0021 | Update of the Product Information to QRD template 9.0 and inclusion of an additional local representative of the MAH for Croatia. The MAH also took the opportunity to make linguistic corrections in the product information of 20 languages.<br><br>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 13/09/2013 | 26/08/2014 | SmPC, Annex II, Labelling and PL | |
| IA/0023 | B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products | 09/09/2013 | 26/08/2014 | SmPC, Labelling and PL | |
| N/0020 | Update of the list of local representatives contact details for Island, Greece, Latvia and Portugal.<br><br>Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 22/01/2013 | 26/08/2014 | PL | |
| IB/0019/G | This was an application for a group of variations.<br><br>B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms<br>B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation | 12/10/2012 | n/a | | |
| N/0017 | Update of the local representatives contact details for | 25/09/2012 | 26/08/2014 | PL | |

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| | Germany and Malta in the package leaflet.<br><br>Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | | | | |
| IG/0184 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 21/08/2012 | n/a | | |
| II/0016 | Change in the active substancfe synthesis<br><br>B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product | 21/06/2012 | 21/06/2012 | | |
| R/0014 | Renewal of the marketing authorisation. | 15/03/2012 | 22/05/2012 | | Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of Aerinaze continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Aerinaze continues to be favourable. The CHMP recommends the renewal of the Marketing Authorisation for Aerinaze for unlimited validity. |
| IG/0117/G | This was an application for a group of variations.<br><br>C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV<br>C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site | 18/11/2011 | 17/02/2012 | Annex II | |

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| | undertaking pharmacovigilance activities<br>C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV<br>C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system | | | | |
| T/0011 | Transfer of MA from SP Europe to Merck Sharp & Dohme Ltd.<br><br>Transfer of Marketing Authorisation | 11/08/2011 | 30/09/2011 | SmPC, Labelling and PL | |
| N/0010 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 04/04/2011 | n/a | PL | |
| IG/0054 | B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer | 11/03/2011 | n/a | | |
| N/0009 | Update of the local representatives contact details for Finland, Spain, Sweden and the Netherlands. The MAH also made minor linguistic changes throughout the Package Leaflets.<br><br>Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 02/02/2011 | n/a | PL | |
| II/0008 | Update of the Detailed Description of the | 21/01/2010 | 15/03/2010 | Annex II | The DDPS has been updated (version 7, December 2009) |

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| | Pharmacovigilance System (DDPS) including change of the Qualified Person for Pharmacovigilance (QPPV). Consequently, Annex II has been updated with the new version number.<br><br>Update of DDPS (Pharmacovigilance) | | | | to reflect the change of the QPPV as well as to notify other changes to the DDPS performed since the last approved version. Consequently, Annex II has been updated including the new version number of the agreed DDPS. The CHMP considers that the Pharmacovigilance System as described by the MAH is acceptable. |
| N/0007 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 22/09/2009 | n/a | PL | |
| N/0006 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 14/04/2009 | n/a | PL | |
| IB/0005 | IB_42_a_01_Change in shelf-life of finished product - as packaged for sale | 20/08/2008 | n/a | SmPC | |
| IB/0004 | IB_33_Minor change in the manufacture of the finished product | 13/08/2008 | n/a | | |
| IB/0002 | IB_10_Minor change in the manufacturing process of the active substance | 09/01/2008 | n/a | | |
| IA/0003 | IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold | 18/12/2007 | n/a | | |
| N/0001 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 12/11/2007 | n/a | Labelling and PL | |