Veterinary Medicines Directorate

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Post Authorisation Assessments

Isofane 100% w/w Inhalation Vapour, Liquid

Vm 37071/4001

•	18 June 2024	Addition of a new testing site for the finished product.
•	04 March 2024	Change to in-process tests or limits applied during the manufacture of the active substance. Changes to the quality part of the dossier. Changes to the quality part of the dossier. Changes to the quality part of the dossier. Minor changes in the manufacturing process of an active substance. Minor changes in the manufacturing process of an active substance. Minor changes in the manufacturing process of an active substance.
•	20 September 2023	Change in test procedure for the finished product: - Other changes to a test procedure.
•	01 September 2023	Change in test procedure for the active substance.
•	10 February 2022	Change in the name of a supplier of starting material used in the manufacture of the active substance. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product.
•	23 December 2021	Minor change in the manufacturing process of the active substance. Change to in-process tests or limits applied during the manufacture of the active substance. Minor change in the manufacturing process of the active substance.
•	18 May 2021	Changes to a test procedure (including replacement or addition) for a starting material.
•	21 April 2021	Deletion of manufacturing site of the manufacturer responsible for batch release.
•	26 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 January 2021	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of the manufacturer of the finished product.
•	09 December 2020	Change in the QPPV of an existing pharmacovigilance

		system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
•	18 September 2020	Increase in batch size of the finished product.
•	05 August 2020	Change in distributor details from Henry Schein, College Mains Road, Dumfries, DG2 ONU to AH UK Animal Health (PVT) Ltd, College Mains Road, Dumfries, DG2 ONU, United Kingdom.
•	23 July 2020	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	13 July 2020	Changes to a test procedure (including replacement) for the active substance.
•	08 July 2020	Change in the manufacturer of a starting material used in the manufacturing process of the active substance.
•	26 February 2020	Update to Part II of the dossier.
•	26 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	25 September 2019	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Minor changes to an approved test procedure of the finished product
•	29 August 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	10 May 2019	Addition of secondary packaging site of the finished product
•	14 January 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	15 November 2018	Change in distributor From, Chanelle Vet UK Ltd., CBX11, 382-390 West Wing, Midsummer Boulevard, Milton Keynes, Buckinghamshire, MK9 2RG, UK, To Henry Schein, College Mains Road, Dumfries, DG2 ONU.
•	25 September 2018	Introduction of a new pharmacovigilance system.
•	22 August 2018	Change in the address of a manufacturer of the active substance. Change in the address of the manufacturer of the finished product. Replacement of a site where testing takes place.
•	07 August 2018	Change in shape or dimensions of the container or closure (immediate packaging).
•	07 December 2017	Change of MAH, from Piramal Healthcare UK Limited, Whalton Road, Morpeth, Northumberland, NE 613YA, United Kingdom to Piramal Critical Care Limited, Suite 4, Ground Floor, Heathrow Boulevard - East Wing, 280 Bath Road, West Drayton, UB7 0DQ, United Kingdom.
•	07 March 2017	Change in the name of a manufacturer of the finished product.
•	26 April 2016	Change in address of the manufacturer of the active substance.

		Change in address of the manufacturer of the finished product.
•	23 December 2014	Change in the batch size of the finished product.
•	14 August 2013	Change of manufacturing site for the active substance Change of manufacturer of the active substance Change of manufacturing site for primary and secondary packaging Change of specification of the finished product Change of specification of the active substance
•	15 March 2012	Change of name of manufacturer of the active substance Change of name of manufacturer of the finished product
•	07 March 2012	Change of address of the distributor
•	01 March 2012	Change of address of the MAH Change of address of the Manufacturing site for batch release
•	10 December 2009	Change of manufacturing site of batch release Change of manufacturing site responsible for quality control
•	02 September 2009	Change of MAH
•	29 April 2009	Change of shelf life from 3 years to 5 years
•	01 April 2009	Change to test methods performed on the active substance
•	11 March 2009	Change of distributor
•	24 February 2009	Addition of a manufacturer responsible for batch release Change of manufacturing site of batch release and importer
•	11 February 2009	Deletion of 2 manufacturers Change of name of manufacturer of the finished product Change of name of manufacturer of the active substance
•	15 January 2009	Renewal
•	22 October 2008	Change of MAH
•	28 August 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	23 April 2008	Change of address of the MAH and Distributor
•	23 August 2008	Renewal
•	05 November 2004	Changes to the SPC and Product Literature to bring in line with new legislation
•	26 February 2003	Change of name and address of the MAH
•	15 July 1999	Addition of a manufacturer for secondary assembly of the finished product