Veterinary Medicines Directorate

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Post Authorisation Assessments

IsoFlo 100% w/w Inhalation Vapour, Liquid

Vm 42058/5102

•	26 June 2023	Alignment of the product information with version 9.0* of the QRD templates.
•	05 May 2023	Change in test procedure for the finished product to comply with Ph. Eur. Minor changes to an approved test procedure for the finished product.
•	05 May 2023	Change in the specification parameters of the finished product. Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product.
•	22 April 2021	Deletion of manufacturing site for a finished product responsible for batch release and site where batch control takes place.
•	12 November 2020	Changes to the SPC and product information to align the wording of documents across EU member states with the authorised UK wording.
•	11 March 2020	Addition of a site where batch control/testing takes place.
•	25 November 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP.
•	02 August 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance (used in manufacturing process of active) from an already approved manufacturer.
•	18 June 2019	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 3 years.
•	13 May 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	14 March 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 April 2018	Change in RMS from UK to ES.
•	26 February 2018	Minor changes to the in-process controls.
•	27 September 2017	Deletion of manufacturing site for a finished product

		manufacturer responsible for batch release
•	07 July 2017	Addition of an in-process test applied during the manufacture of the active substance.
•	09 June 2017	Repeat Use application to add 4 new member states
•	29 December 2016	Change in the address of the marketing authorisation holder in France, Czech Republic & Slovakia.
•	22 September 2016	Renewal – UK as RMS
•	17 December 2015	Submission of a new certificate of suitability.
•	30 July 2015	Introduction of a new pharmacovigilance system.
•	27 July 2015	Change of MAH, from Abbott Laboratories Ltd to Zoetis UK Limited. Addition of a distributor.
•	06 June 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	21 March 2013	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	18 August 2011	Introduction of a new pharmacovigilance system
•	12 August 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	05 July 2011	Repeat use procedure
•	27 November 2009	Change of address of the MAH
•	31 July 2009	Addition of a manufacturing site for batch release Addition of a manufacturing site for secondary packaging
•	06 April 2009	Removal of test procedure performed on the active substance
•	10 February 2009	Change of name of manufacturing site of the finished product, batch control and batch release Submission of a new Ph. Eur. Certificate of Suitability for the active substance
•	06 August 2008	Renewal
•	27 February 2007	Change of legal category from POM to POM-V
•	30 January 2004	Renewal
•	27 February 2002	Deletion of a distributor
•	14 December 2000	Repeat use procedure to include AT, BE, ES, FI, LU & PT
•	27 July 1999	Change of distributor Changes to the Product Literature
•	23 February 1999	Change to formulation
•	14 May 1998	Mutual Recognition Procedure, UK as RMS