Veterinary Medicines Directorate

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Post Authorisation Assessments

IsoFlo 100% w/w Inhalation Vapour, Liquid

Vm 42058/5102

05 March 2025	Deletion of a pack size of the finished product. Replacement of a manufacturer responsible for batch release not including batch control or testing of a sterile or non-sterile finished product.
03 January 2025	Reduction in the testing frequency of an analysis. Replacement of a manufacturing site for part or all of the manufacturing process of the finished product.
25 June 2024	Deletion of a Ph. Eur. CEP for an active substance.
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