Veterinary Medicines Directorate

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Post Authorisation Assessments

Iso-Vet 1000 mg/g Inhalation Vapour, Liquid

Vm 37071/4000

•	07 November 2023	Change in test procedure for the finished product.
•	27 October 2023	Change in test procedure for the active substance.
•	21 December 2022	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	21 December 2022	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	21 December 2022	Change in the pharmacovigilance system master file (PSMF) location.
•	21 December 2022	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	02 March 2022	Minor change in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance. Changes in the manufacturing process of the active substance.
•	13 January 2022	Addition of a supplier of packaging components or devices. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Name change of the supplier of immediate packaging.
•	23 November 2021	Addition of piglets as a target species.
•	26 August 2021	Deletion of manufacturing site for a manufacturer responsible for batch release and a site where batch control takes place.
•	08 April 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	04 March 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.
•	26 January 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	23 November 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.
•	06 November 2020	Increase in batch size of the finished product: 100 ml pack size from 1500 Kg to 4000 kg and 250 ml pack size from 3000 kg to 4000 kg
•	22 September 2020	Change in manufacturer of active substance.

•	18 August 2020	Changes to a test procedure for the active substance.
•	29 May 2020	Update to Part II of the dossier.
•	15 October 2019	Minor changes to an approved test procedure of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	02 October 2019	Introduction of a new pharmacovigilance system.
•	16 September 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	05 June 2019	Replacement of a site where batch testing takes place.
•	12 April 2019	Replacement of a manufacturer responsible for batch release of the finished product.
•	31 January 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	24 December 2018	Introduction of a new pharmacovigilance system
•	26 November 2018	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	21 September 2018	Change in the address of a manufacturer used in the manufacture of the active substance. Change in the address of the manufacturer of the finished product. Replacement of a site where batch control/testing takes place.
•	21 September 2018	Change in shape or dimensions of the container or closure (immediate packaging).
•	18 December 2017	Change in the RMS from UK to NL.
•	03 August 2017	Change of MAH from Piramal Healthcare UK Limited to Piramal Critical Care Limited.
•	05 April 2017	Change in the name of a manufacturer of the finished product.
•	11 March 2016	Change in the address of the manufacturer of the active substance. Change in the address of the manufacturer of the finished product.
•	13 November 2014	To increase the batch size of the finished product, from 1500 kg to 3000 kg.
•	16 October 2014	Deletion of a distributor.
•	08 August 2014	Renewal procedure – UK as RMS.
•	01 August 2014	Change to the back-up QPPV. Minor changes to the DDPS.
•	25 April 2013	Change in the name of manufacturer of finished product. Change in the name of manufacturer of the drug substance.
•	12 April 2013	Tightening of in-process fill limit during the manufacture of the finished product. Tightening of specification limits of finished product.
•	20 June 2012	To add a Distributor.
•	12 January 2012	Change of the Marketing Authorisation Holder and batch release site.
•	12 January 2012	Changes to the batch release arrangements and quality control testing of the finished product.

•	16 September 2011	Repeat Use procedure. UK as RMS.
•	10 August 2011	To change the SPC, labeling and package leaflet according to another similar product.
•	03 June 2011	Removal of the impurities from the active substance specification.
•	03 June 2011	Removal of the impurities from the finished product specification.
•	03 June 2011	Change in batch size from 3500-4200 kg to 6300 – 7700 kg.
•	03 June 2011	Change in the manufacturing process of the active substance.
•	21 December 2009	To change the name of the active substance manufacturer and finished product manufacturer.
•	21 December 2009	To change the name and address of contract quality control testing site.
•	21 December 2009	To change the name of the quality control testing site.