Veterinary Medicines Directorate

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Post Authorisation Assessments

Imizol 85 mg/ml Solution for Injection

Vm 06376/4080

19 December 2024	Approval of mock ups.
21 October 2024	Replacement and addition of test procedure for an excipient. Change in the specification parameters of an excipient.
28 June 2024	Change in legal entity of the MAH from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ, United Kingdom to Intervet International BV, Wim de Korverstraat 35, 5831 AN, Boxmeer, Netherlands.
04 July 2023	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier: - Introduction of a manufacturer of the active substance supported by an ASMF.
08 September 2022	Change in the outer packaging. Minor changes to SPC and QRD texts.
21 June 2022	Change in number of vials per pack.
13 April 2022	Changes to package leaflet to update contact information for the APHA.
08 October 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product
14 July 2021	Minor change in the manufacturing process of the finished product.
01 April 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
04 May 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
16 May 2013	Change to the specification of the finished product Change to test procedure performed on the finished product
14 December 2011	Changes to the SPC and Product Literature
28 October 2011	Changes to a test procedure performed on the finished product
22 September 2011	Change of MAH and Distributor
22 August 2011	Change to specification of the active substance Removal of test procedure performed on the active substance

16 February 2011	Removal of test procedure performed on a starting material used in the production of the finished product
23 November 2010	Change of name of manufacturing site of the finished product
15 June 2010	Change of shelf life from 24 months to 18 months
05 May 2010	Change of shelf life
27 May 2009	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
06 October 2006	Renewal
26 February 2003	Renewal
26 February 2003	Change of withdrawal period for meat from cattle from 90 days to 213 days
17 November 1997	Change to manufacturer of the active substance