Veterinary Medicines Directorate

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Post Authorisation Assessments

Finadyne 50 mg/ml Solution for Injection

Vm 06376/4088

09 July 2026	Change in the name or address or contact details of a manufacturer or importer of the finished product.
19 May 2026	Addition of a secondary packaging site of the finished product.
19 May 2026	Addition of a manufacturing site of the finished product. Change in the specification parameters and/or limits of an excipient where there is no monograph in the European Pharmacopoeia. Addition of a test procedure for the finished product. Change in shape or dimensions of the immediate packaging of the finished product.
14 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (GB)
14 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
17 December 2025	Harmonisation of Part II following SPC harmonisation.
27 November 2025	Approval of mock-ups.
10 October 2025	Change in test procedure for the finished product to comply with Ph. Eur.
10 October 2025	SPC harmonisation.
22 December 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
10 December 2024	Change in legal entity from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes MK7 7AJ to Intervet International B.V., Wim de Korverstraat 35, 5831 AN, Boxmeer, Netherlands.
04 October 2023	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.
07 June 2022	Update SPC/QRD in line with CMDv outcome on Toxicity of veterinary medicinal products containing flunixin meglumine on scavengers.
08 March 2022	Changes to SPC and product literature following a periodic safety update report.
28 April 2021	Change in name of the MAH from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
18 November 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
28 June 2019	Replacement to a test procedure for the finished product.

	Addition of a test procedure for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Replacement of an excipient with a comparable excipient. Replacement of an excipient with a comparable excipient.
14 March 2018	Change in the address of the ASMF holder. Addition of a new specification parameter to the specification with its corresponding test method. Deletion of a non-significant specification parameter.
23 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability from an already approved manufacturer.
24 July 2014	Change in part of the primary packaging material not in contact with the finished product formulation.
13 June 2013	Change of name of Active Substance Master File (ASMF) holder Change of re-test period of the active substance Submission of an updated ASMF
01 August 2012	Update to sections 4.3, 4.5 and 4.7 of the SPC
25 July 2012	Submission of a new Ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer
15 February 2012	Change of MAH
23 February 2011	Addition of a manufacturer of the active substance
12 September 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
07 March 2007	Renewal
13 December 2006	Addition of a manufacturer of the active substance
24 August 2005	Minor change to the manufacturing process of the active substance
22 July 2004	Renewal
06 November 2003	Addition of Pigs to target species
31 October 2003	Change of withdrawal period for milk from cattle from 12 hours to 24 hours
18 March 2003	Change to test procedure performed on the finished product
25 September 2002	Minor change to manufacturing process of the active substance
30 November 2001	Change of manufacturer of the dosage form
20 September 1999	Renewal
16 August 1996	Change of withdrawal period