Veterinary Medicines Directorate

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Post Authorisation Assessments

Finadyne 50 mg/g Oral Paste

Vm 01708/4599

•	18 October 2022	Update SPC/QRD in line with CMDv outcome on Toxicity of veterinary medicinal products containing flunixin meglumine on scavengers.
•	01 June 2022	Change in the name or address of a manufacturer of the finished product.
•	27 May 2022	Editorial update of SPC. Changes to labelling or packaging leaflet not connected to SPC.
•	01 April 2022	Deletion of a pack size(s) of the finished product. Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the invented name of the veterinary medicinal product from Finadyne 5% w/w Oral Paste to Finadyne 50 mg/g Oral Paste. Replacement of a specification parameter with its corresponding test method of the finished product.
•	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.
•	04 April 2019	Addition of a site where batch control/testing takes place.
•	08 January 2016	Change in test procedure for the finished product Change in the specification parameters and/or limits of the finished product
•	21 September 2015	Change in batch control/testing, secondary & primary packaging sites. Change in test procedure and batch size of the finished product. Addition of a new manufacturing site of the finished product.
•	15 January 2015	Submission of a new Ph. Eur. Certificate of Suitability for the active substance.
•	03 December 2014	Deletion of a manufacturing site for the active substance.
•	04 August 2014	Change in the batch size of the finished product.
•	25 October 2013	Change of distributor. Change of manufacturer for assembly of the dosage form. Change to packaging layout. Change of MAH.
•	22 July 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 August 2008	Renewal.
•	13 December 2006	Addition of a manufacturer of the active substance.
•	24 August 2005	Change of composition of the packaging. Minor change of manufacturing process of the active substance.
•	08 December 2004	Renewal.
•	21 March 2003	Change of tests performed on the active substance.
•	25 September 2002	Change of manufacturing process of the active substance.
•	07 December 2000	Renewal.
•	15 July 1998	Renewal. Change to safety warnings.