Veterinary Medicines Directorate

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Post Authorisation Assessments

Finadyne 50mg/ml Solution for Injection

Vm 01708/4582

•	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