Veterinary Medicines Directorate

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Post Authorisation Assessments

Finadyne Transdermal 50 mg/ml Pour-on Solution for Cattle

Vm 01708/5080

•	07 March 2024	Addition of a new manufacturer of the active substance via submission of a Ph. Eur. CEP.
•	19 May 2023	Change(s) in the SPC, labelling or package leaflet to section 4.5. Alignment of the product information with version 9.0* of the QRD templates.
•	17 May 2023	Change in the specification limits of the immediate packaging of the finished product.
•	22 March 2023	A change in the primary packaging material not in contact with the finished product formulation: lining material.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	20 November 2019	Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	11 June 2019	Renewal UK as CMS
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	14 March 2018	Change in address of the Active Substance Master File holder. Addition of a new specification parameter Addition of a new specification parameter Addition of a new specification parameter Deletion of a non-significant parameter Deletion of a non-significant parameter
•	18 January 2017	Minor change in the manufacturing process of the finished product.
•	29 December 2016	Addition of a new therapeutic indication.
•	01 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	21 August 2015	Change to therapeutic indications.
•	19 June 2015	Change in dimensions of container. (immediate packaging)
•	26 March 2015	Submission of an updated certificate of suitability.
•	27 November 2014	Update of the pharmacovigilance system as described in the DDPS.