Veterinary Medicines Directorate

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Post Authorisation Assessments

Relaquine 35 mg/ml Oral Gel for Horses

Vm 56190/3001

•	11 May 2023	Change in batch size of the finished product.
•	03 February 2023	Replacement of a quality testing site for the finished product.
•	21 December 2022	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	23 February 2022	Change in the name and address of the marketing authorisation holder in Northern Ireland from Floris Animal Health Ltd., Bath House 6-8, Bath Street, Bristol, BS1 6HL, United Kingdom to Floris Holding BV, Kempenlandstraat 33 / 35, 5262 GK Vught, The Netherlands.
•	16 July 2021	Addition of device with CE markings which is not an integrated part of the primary packaging.
•	09 October 2020	Changes to the labelling and package leaflet.
•	27 July 2020	Repeat Use application to add 4 new member states.
•	04 May 2020	Change of MAH from Floris Veterinaire Produkten BV, Kempenlandstraat 33 / 35, 5262 GK Vught, Netherlands to Floris Animal Health Ltd., Bath House 6-8, Bath Street, Bristol, BS1 6HL, United Kingdom.
•	08 April 2020	Increase in batch size of the finished product. Change in type of container for the finished product. Addition of a new container for the finished product. Change in the fill volume of the finished product. Increase in the shelf-life of the finished product after first opening, from 28 days to 90 days.
•	24 December 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	20 December 2018	Change in RMS from UK to NL.
•	27 September 2018	Addition of details on use of the product in the Summary of Product Characteristics and Package Leaflet.
•	14 August 2017	Replacement of a site where batch control/testing takes place.
•	01 August 2016	Renewal – UK RMS.
•	08 July 2015	Changes to the labelling and package leaflet.
•	23 April 2015	Change to the withdrawal period wording. Change to the name of the product in Sweden only.
•	14 March 2012	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.

•	14 March 2012	Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance.