Veterinary Medicines Directorate

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Post Authorisation Assessments

Relaquine 35 mg/ml Oral Gel for Horses

Vm 56190/3001

3 August 2026	Minor amendments to product literature - clarification that target species is non-food producing horses plus user warnings re hypersensitivity.
13 May 2026	SRP to add 7 CMS.
02 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Change in the pharmacovigilance system master file (PSMF) location.
02 December 2025	Other changes to the active substance: - Substantial changes in the updated version of the ASMF.
26 February 2025	Change outside the approved specifications limits range.
18 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
30 December 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
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.