Veterinary Medicines Directorate

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Post Authorisation Assessments

Rifen 100 mg/ml Solution for Injection for Horses, Cattle and Pigs

Vm 57446/5000

•	07 March 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	18 October 2023	Change in Distributor details, from Chanelle Vet UK Ltd, 1st Floor Freemans House, Hungerford, Berkshire, RG17 0DL to Chanelle Vet UK Ltd, 483 Green Lanes, London, N13 4BS.
•	15 June 2023	Change in name of the manufacturer of the finished product.
•	07 June 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	27 April 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	23 January 2023	Change in MAH from Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria to VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria.
•	17 February 2022	Changes to the withdrawal period of the veterinary medicinal product.
•	15 February 2022	Addition of a new therapeutic indication.
•	04 October 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	13 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 July 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	11 January 2017	Addition of a new Ph. Eur. certificate of suitability for an active substance.
•	29 June 2016	Deletion of an API manufacturer for the finished product. Addition of an API manufacturer for the finished product.
•	16 August 2013	Change in name of veterinary medicinal product to: Rifen 100mg/ml Solution for Injection for Horses, Cattle and Swine.
•	15 July 2013	Change of distributor details
•	22 April 2013	Renewal procedure – Austria as RMS.
•	08 May 2012	Repeat Use to add additional Member States
•	05 January 2012	Changes to an existing pharmacovigilance system as described in the DDPS.

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•	05 January 2012	Submission of a new or updated Ph. Eur.Certificate of Suitability.
•	14 December 2012	To add a new therapeutic indication for swine.
•	06 July 2011	Submission of a new or updated Ph. Eur.Certificate of Suitability.
•	06 July 2011	Submission of a new or updated Ph. Eur.Certificate of Suitability.
•	12 March 2010	Repeat Use Procedure.