



Post Authorisation Assessments

Equizol 400 mg Gastro-resistant Granules for Horses Vm 20916/4023

•	20 June 2024	Change in distributor details from Animalcare Ltd., 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB , United Kingdom to Grovet B.V., Centurionbaan 140, 3769 AV Soesterberg, The Netherlands. Approval of mock-ups.
•	20 May 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (NI)
•	28 April 2024	Addition of local representative Grovet B.V., Centurionbaan 140, 3769 AV Soesterberg, The Netherlands.
•	04 May 2023	Substantial changes to the finished product manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product.
•	17 April 2023	Submission of a new CEP from an already approved manufacturer for a non-sterile: active substance. (GB)
•	17 August 2022	Unlimited renewal.
•	21 December 2020	Replacement of a site where batch control/testing takes place.
•	25 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	29 August 2019	Changes to the labelling and package leaflet.
•	20 August 2019	Change of distributor.
•	10 April 2019	Change in the invented name of the veterinary medicinal product from Equizol 400 mg gastro-resistant granules for horses to Hippozol vet 400 mg gastro-resistant granules for horses in DK
•	10 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 October 2018	Change in RMS from UK to DE.