



Post Authorisation Assessments

Omeproshield 370 mg/g Oral Paste for Horses Vm 08327/4263

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| • | 11 April 2023 | Change in the name or address or contact details of a qualified person for pharmacovigilance. |
| • | 31 January 2023 | Change in address of manufacturer of the finished product. |
| • | 16 August 2022 | Change in address of manufacturer of the finished product. |
| • | 01 December 2021 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 22 October 2021 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 28 May 2020 | Change in the name and address of a manufacturer of the finished product, also responsible for batch release. |
| • | 19 March 2020 | Renewal - UK as CMS. |
| • | 05 November 2019 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 23 September 2019 | Change of distributor from Newmarket Equine, Hospital, Cambridge Road, Newmarket, Suffolk, CB8 0FG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom. |
| • | 07 February 2019 | Change in the name of the manufacturer of the finished product. |
| • | 16 November 2018 | Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom. |
| • | 26 June 2018 | Change in RMS from UK to IE. |
| • | 06 February 2018 | Submission of a new Ph. Eur. Certificate of Suitability for an active substance from a new manufacturer. |
| • | 09 August 2017 | Deletion of manufacturing site for an active substance. |
| • | 09 August 2017 | Change in the specification limits of the finished product. |
| • | 15 June 2017 | Changes to a test procedure for the active substance. |
| • | 06 April 2017 | Change to part of the packaging material not in contact with the finished product formulation. |
| • | 13 January 2017 | Submission of an updated certificate of suitability. |
| • | 28 September 2016 | Approval of mock-ups. Change in distributor details. From Merial Animal Health |

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| | | Ltd. to Newmarket Equine Hospital. |
| • | 08 December 2015 | Change in the QPPV and/or QPPV contact details and/or back-up procedure |