

VPA10454/071/001

**Omeproshield 370 mg/g oral paste for horses**

| Variation         | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Date     |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Vet - B3 t)       | VNRA - Vet - B3 t) - - Vet - B3 t) - Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance;— for a starting material, reagent or intermediate used in the manufacturing process of the active substance;— for an excipient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 25/07/25 |
| Vet - B38         | VNRA - Vet - B38 - - Vet - B38 - Change in pack size (number of units e.g. tablets, ampoules, etc. in a pack) within the range of the currently approved pack size                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 24/06/25 |
| Vet - B47 c)      | VNRA - Vet - B47 c) - c) Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur. - B47 c) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 09/06/25 |
| Vet - F.II.e.2 z) | VRA-R - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021                                                                                                                                                                                                                                                                                                                                                                                                                  | 06/06/25 |
| Vet - F.II.d.1 a) | VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 06/06/25 |
| Vet - F.IV.1 b)   | VRA-S - Vet - F.IV.1 b) - b) Addition or replacement of a device which is an integrated part of the primary packaging - F.IV.1 b) Quality Changes - Devices - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 06/06/25 |
| Vet - G.I.18      | VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products | 28/03/24 |

|             |                                                                                                                                                                                                                                                                                                                                                                                                          |          |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
|             | placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004                                                                                                                                                                                                                                                                                                              |          |
| Vet - C6    | VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6<br>Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 | 07/07/23 |
| Vet - C1    | VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1<br>Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)                                                                                       | 07/07/23 |
| Vet - A1 e) | VNRA - Vet - A1 e) - e) Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites) - A1 e) Administrative changes: Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites)              | 08/08/22 |
| Vet - A1 a) | VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administrative changes: Change in the name or address or contact details of the marketing authorisation holder                                                                                                                                                                    | 08/08/22 |