



## Post Authorisation Assessments

### Distocur 34 mg/ml Oral Suspension for Cattle and Sheep Vm 28365/3002

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| 20 January 2026   | Deletion of a non-significant specification parameter of an active substance.   |
| 25 February 2025  | Addition of a manufacturer responsible for batch release of the finished product.   |
| 25 February 2025  | Addition of a secondary packaging site of the finished product.   |
| 11 January 2025   | Change in dimensions of the container of the finished product.  |
| 23 November 2023  | One-off alignment of the product information with version 9.0 of the QRD templates.   |
| 27 January 2023   | Deletion of a manufacturing site of the active substance.   |
| 07 December 2022  | Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.    |
| 08 July 2022      | Deletion of a manufacturing site of the active substance.   |
| 25 January 2022   | Increase in batch size (up to 10-fold) of the finished product.   |
| 12 August 2021    | Renewal – UK as CMS.  |
| 19 June 2020      | Change in the name and address of a manufacturer of the finished product, also responsible for batch release.   |
| 07 January 2020   | Introduction of a new pharmacovigilance system  |
| 04 September 2019 | Change of distributor from: Boehringer Ingelheim Animal Health UK Limited to Duggan Veterinary Supplies Limited.  |
| 09 August 2019    | Change in MAH from: Boehringer Ingelheim Animal Health UK Ltd<br>Ellesfield Avenue<br>Bracknell<br>Berkshire<br>RG12 8YS<br>to:<br>Dopharma Research B.V.<br>Zalmweg 24<br>4941 VX Raamsdonksveer<br>The Netherlands  |
| 2 July 2019       | Addition of sheep as a new target species.  |
| 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. |
| 30 January 2018   | Increase in the shelf-life of the finished product after first opening, from 3 months to 1 year.  |

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| 30 January 2018 | Changes to the SPC/product labelling/package leaflet following an Article 35 referral.   |
| 10 April 2017   | Deletion of a non-significant in-process test applied during the manufacture of the finished product.<br>Deletion of a non-significant in-process test applied during the manufacture of the finished product. |