Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Distocur 34 mg/ml Oral Suspension for Cattle and Sheep

Vm 28365/3002

11 August 2026	Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
06 August 2026	Change in the dimensions of the container.
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 Ellesfield Avenue Bracknell Berkshire RG12 8YS to: Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer 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.
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. Deletion of a non-significant in-process test applied during the manufacture of the finished product.