



Post Authorisation Assessments

Cocci-Drench 2.5 mg/ml Oral Suspension Vm 06376/5036

25 March 2025	Change in legal entity from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
07 January 2025	Change in immediate packaging of the finished product. Change in test procedure for the finished product. Change in the specification parameters and/or limits of an active substance. Change in the specification parameters and/or limits of an excipient: - Other changes. Change in the specification limits of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in packaging configuration. Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics. Replacement of a manufacturing site for the manufacturing process of the finished product.
14 December 2024	Change to comply with Ph. Eur. in the specification of excipient. Replacement of a manufacturer responsible for batch release including batch control or testing of non-sterile finished product. Replacement of a primary packaging site of a non-sterile finished product. Replacement or addition of a secondary packaging site of a finished product.
01 December 2024	Addition of a new testing parameter to the specification of the immediate packaging of the finished product.
12 January 2024	Change in the batch size of the finished product.
05 December 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
19 July 2023	Unlimited renewal
13 January 2023	Updated certificate of suitability from an already approved manufacturer.
13 January 2022	Introduction of a new pharmacovigilance system.
30 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
01 October 2020	Change of MAH, from Elanco Europe Ltd., Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.

