Veterinary Medicines Directorate

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Post Authorisation Assessments

Cydectin 0.1% w/v Oral Solution for Sheep

Vm 42058/5133

•	10 July 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	18 May 2024	Change in test procedure for ID and assay of moxidectin. Change in test procedure for content of benzyl alcohol. Change in test procedure for content of BHT. Change in specification parameters for identification of benzyl alcohol, BHT and EDTA. Change in the finished product specification limit for volume. Harmonisation of the quality dossier.
•	22 December 2023	Change(s) in the SPC, labelling or package leaflet to sections 4.4 and 4.9 - updated resistance statements and prudent use warnings.
•	14 July 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	21 February 2023	Change in 2.5 L immediate packaging of the finished product.
•	20 February 2023	Change in dimensions of the closure of immediate packaging of a non-sterile finished product.
•	13 May 2022	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
•	01 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 January 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	19 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 February 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.

•	09 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 November 2016	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	23 July 2015	Submission of a new certificate of suitability from a new manufacturer.
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	10 October 2014	Change in the batch size (including batch size ranges) of the finished product, from 5000 litres to a range of 5000 to 6000 litres.
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	30 October 2013	Grouped variation to change the name of an active substance manufacturer, the manufacture responsible for finished product and batch release, and the QPPV contact details.
•	22 October 2013	Variation to change the name and address of the Marketing Authorisation Holder in Austria, Belgium, France and Luxembourg only.
•	12 August 2013	Grouped variation to change the Marketing Authorisation Holder.
•	13 June 2012	Variation to change the DDPS.
•	04 November 2011	Variation to change the name of the manufacturer responsible for batch release.
•	02 September 2011	Submission of a new Ph. Eur. Certificate of suitability.
•	13 January 2011	Renewal.
•	11 May 2010	Change of Marketing Authorisation Holder.
•	09 February 2009	Comply with Ph. Eur. or MS national pharmacopoeia: former non EU (active).