Veterinary Medicines Directorate

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

Post Authorisation Assessments

Cydectin 10% LA Solution for Injection for Cattle

Vm 42058/5116

07 August 2025	Extension of a re-test period/storage period supported by real time data.
04 February 2025	Changes in the composition of the finished product.
10 July 2024	Update of sections 4.4, 4.5, 4.6 and 4.9 to implement the outcome of a procedure concerning risk management measures in pharmacovigilance.
06 November 2023	Alignment of the product information with version 9.0* of the QRD templates.
03 August 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
05 September 2022	Change in flange height of the aluminium cap on the finished product.
28 January 2021	Change in batch size of the finished product.
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.
23 September 2019	Minor changes to an approved test procedure of the finished product.
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 September 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging).
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.
13 January 2017	Submission of a new certificate of suitability for an active substance.
04 August 2016	Variation to implement changes in the product information as requested by the RMS as a result of the review of PSUR.
10 July 2015	Submission a new Ph. Eur. Certificate of Suitability for the active substance.
05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
04 July 2014	Submission of an updated Ph. Eur. Certificate of suitability.

30 October 2013	Change in the name of manufacturer of the finished product and batch release. Change in QPPV contact details.
23 October 2013	Change of Marketing Authorisation Holder in Belgium, France and Luxembourg only.
12 August 2013	Change of Marketing Authorisation Holder and distributor.
04 November 2011	Change to the name of a manufacturer of the finished product.
02 September 2011	Submission of a new or updated certificate of suitability.
14 December 2011	Change of Marketing Authorisation Holder from Fort Dodge Animal Health Ltd to Pfizer Ltd.
19 October 2010	Renewal – UK as CMS
05 November 2009	To increase the shelf life, widen the specification limits for benzyl alcohol at end of shelf-life and inclusion of extra tests in the finished product shelf-life specification.
09 February 2009	Variation to comply with Ph. Eur. to change the specifications of the active substance.