Veterinary Medicines Directorate

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

Post Authorisation Assessments

Cydectin TriclaMox 5 mg/ml + 200 mg/ml Pour-on Solution for Cattle

Vm 42058/5112

•	18 May 2024	Deletion of a manufacturing site for an intermediate of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	09 November 2023	One-off 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.
•	22 December 2020	Update of SPC and package leaflet text as assessed under Regulation 1901/2006.
•	01 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 May 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 April 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.
•	15 June 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	02 June 2017	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	16 December 2016	Renewal – UK as CMS
•	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	Increase to the batch size of an active substance, from 220±10 kg to 440±20 kg.
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of suitability.
•	13 November 2013	Changes to therapeutic indications.
•	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 name of MAH in Austria, Belgium, France and Luxembourg only.
•	12 August 2013	Change of MAH and distributor.
•	21 March 2013	Amendments to the SPC and product literature to comply with the outcome of an EU Directive.
•	10 December 2012	Addition of text to section 4.2 of the Summary of Product Characteristics (SPC).