Veterinary Medicines Directorate

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Post Authorisation Assessments

Zermex 0.5% w/v Pour-on Solution for Cattle

Vm 42058/4170

•	13 April 2024	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	17 March 2023	Updates to Section 4.3, 4.5 and 4.6 of the SPC and the corresponding sections in the PL.
•	23 March 2021	Change in distributor details. From Downland Marketing Limited, 15 Victoria Place, Carlisle, Cumbria, CA1 1EW to Downland Marketing Limited, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, Cumbria, CA4 8RR.
•	06 November 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.
•	09 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	26 November 2019	Change in the specification parameters of an excipient.
•	17 April 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	18 December 2018	Change in the specification parameters of an excipient
•	23 October 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	12 April 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral. Changes to the labelling and package leaflet.
•	24 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	17 June 2015	Submission of a new certificate of suitability for a new manufacturer.
•	20 April 2015	Change to the QPPV contact details.
•	20 May 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	23 August 2013	Change to the name for the active substance manufacturer and for the manufacturer of the finished product responsible for batch release.
•	30 July 2013	Transfer of MA from Pfizer Ltd to Zoetis UK Limited.
•	16 November 2013	To change the withdrawal period for milk to 6 days (144 hours).
•	06 July 2011	Change in the name of the manufacturer of the finished

		product.
•	22 June 2011	Submission of a new Ph. Eur certificate of suitability from an already approved manufacturer of the active substance.
•	07 July 2010	Changes to the finished product specification.
•	26 May 2010	Transfer of MA from Fort Dodge Animal Health Ltd to Pfizer Limited.
•	12 May 2010	Updates to the SPC and product literature.
•	21 January 2009	Changes to comply with the newly published European Pharmacopoeia.
•	31 July 2008	Changes to bring the SPC and product literature in line with new legislation and to transfer the legal category from PML to POM-VPS.
•	01 September 2006	Renewal.
•	15 November 2004	Addition of a new 5 litre presentation.
•	15 November 2004	Increase in batch size.
•	15 November 2004	Change to the manufacturing process.
•	12 December 2002	Changes to the manufacturing process for the active substance.
•	03 May 2002	Change to the name and address of a manufacturer.
•	03 May 2002	Changes to the finished product specification.
•	03 May 2002	Change to the manufacturing process.