Veterinary Medicines Directorate

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Post Authorisation Assessments

Zermex 1% w/v Solution for Injection for Sheep

Vm 42058/4171

•	18 March 2024	Change in any part of the primary packaging material not in contact with the finished product formulation. Changes to the quality part of the dossier: Deletion of a non-significant specification parameter.
•	21 December 2022	Change in any part of the primary packaging material not in contact with the finished product formulation.
•	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.
•	24 April 2019	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)
•	15 March 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	01 December 2016	Submission of a new Ph. Eur. Certificate of Suitability for the active substance.
•	15 July 2015	Submission of a new Ph. Eur. Certificate of Suitability.
•	20 April 2015	Change to the QPPV contact details.
•	06 August 2014	Changes to the text on the immediate labels.
•	20 May 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.

•	23 August 2013	Grouped variation to change the API manufacturer and the name of the finished product manufacturer (responsible for batch release).
•	30 July 2013	Variation to transfer the Marketing Authorisation Holder.
•	06 July 2011	Variation to change the name of the manufacturer and assembler of dosage form.
•	22 June 2011	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	25 March 2011	Deletion of a test parameter for the finished product specifications.
•	26 May 2010	Variation to change the Marketing Authorisation Holder.
•	15 May 2010	Addition of text to the SPC and Package Leaflet.
•	21 January 2009	Variation to update the specification of the active substance to comply with the newly publish European Pharmacopoeia Monograph.
•	21 August 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	24 January 2006	Renewal.
•	05 December 2002	Change in the manufacturing process.