



Post Authorisation Assessments

Zermex 0.1% w/v Oral Solution for Sheep Vm 42058/4169

•	13 April 2024	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	12 January 2024	Change in immediate packaging of the finished product: - Qualitative and quantitative composition - non-sterile liquid pharmaceutical forms. Updates to the SPC including updated resistance warnings and statements.
•	12 January 2024	Change in dimensions of the container of a non-sterile finished product.
•	28 July 2022	Variation to change the composition of the 5L container. Variation to change the dimensions of the 5L container.
•	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.
•	17 April 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	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.
•	13 November 2014	Change to increase the batch size of the finished product, from 5000 litres to a range of 5000 to 6000 litres.
•	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 of the active substance manufacturer and change to the name of the manufacturer of the finished product responsible for

		batch release.
•	30 July 2013	Transfer of MA from Pfizer Ltd to Zoetis UK Limited.
•	06 July 2011	Change to the name of a manufacturing site.
•	22 June 2011	Submission of a new Ph. Eur certificate of suitability for an already approved manufacturer of the active substance.
•	26 May 2010	Transfer of MA from Fort Dodge Animal Health Ltd to Pfizer Limited.
•	12 May 2010	Updates made to the SPC and product literature.
•	09 June 2009	Renewal.
•	21 January 2009	Changes to comply with the European Pharmacopoeia.
•	21 August 2008	Changes to bring the SPC and product literature in line with new legislation and to change the legal category from PML to POM-VPS.
•	02 November 2005	To decrease the withdrawal period to 14 days for meat and offal and 5 days for milk.
•	12 September 2005	Renewal.
•	05 December 2002	Changes to the manufacturing process for the active substance.