



Post Authorisation Assessments

Zermasect Sheep Pour-on Alphacypermethrin 12.5 g/l Pour-on Solution Vm 42058/4168

•	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.
•	28 July 2020	Change in shape or dimensions of the container or closure (immediate packaging).
•	02 June 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, First Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. Changes to the labelling and package leaflet.
•	14 January 2020	Change in shape or dimensions of the container or closure (immediate packaging)
•	27 August 2019	Increase in batch size, from 1000-4000 litres to a range of 1000-5900 litres, of the finished product.
•	23 October 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 August 2018	Change in the address of the manufacturer of the active substance.
•	04 July 2017	Tightening of specification limits used in the manufacturing process of the active substance Tightening of specification limits used in the manufacturing process of the active substance Tightening of specification limits used in the manufacturing process of the active substance Change in test procedure for active substance
•	13 November 2015	Change in test procedure for active substance
•	20 April 2015	Change to the QPPV contact details.
•	15 January 2015	Change to the shelf-life of the veterinary medicinal product as packaged for sale, from 18 months to 24 months.
•	08 May 2014	Change in MAH and change in name of manufacturer of the finished product.
•	15 February 2013	Renewal – Informed consent.
•	14 December 2011	To update the meat withdrawal period to maintain consistency with the parent product.
•	31 August 2011	To change the storage conditions of the product.
•	29 June 2011	Replacement or addition of a manufacturing site for

		part or all of the manufacturing process of the finished product.
•	21 June 2011	Manufacturer (active)
•	21 June 2011	Change to batch release arrangements and quality control testing of the finished product.
•	20 June 2011	To change the assembler of the finished product.
•	26 May 2010	To change the MAH from Fort Dodge Animal Health Ltd to Pfizer Limited.