



Post Authorisation Assessments

Dysect Sheep Pour-on, Alphacypermethrin 12.5 g/l Pour-on Solution Vm 42058/4055

•	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.
•	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
•	15 January 2015	Change to the shelf-life of the veterinary medicinal product as packaged for sale, from 18 months to 24 months.
•	20 February 2014	Change of MAH, from Pfizer to Zoetis. Change in distributor details. Change in the name of the manufacturer of the finished product (including batch release).
•	11 October 2012	Increase in batch size.
•	02 September 2011	Change in storage conditions to avoid extremes of temperatures and to not freeze. Renewal.
•	29 June 2011	Change of manufacturer of the finished product.
•	21 June 2011	Change of manufacturer of the active substance.
•	20 June 2011	Change of primary packaging site of the finished product. Change of site of batch release.
•	24 June 2010	Change of MAH.
•	17 January 2008	Change of legal category from PML to POM-VPS. Changes to the SPC and Product Literature to bring in line with new legislation.
•	20 December 2005	Addition of safety warning concerning discolouration of

		the fleece.
•	04 March 2005	Change in colouring system of the product.
•	04 February 2005	Addition of precautionary statement on the SPC and product Literature to optimise dosing.
•	27 May 2004	Changes to labels and removal of outer box.
•	21 November 2003	Addition of 5 Litre pack sizes.
•	07 March 2003	Removal of the 3 Litre pack size. Change of product name from 'Renegade Sheep Pour-on' to 'Dysect Sheep Pour-On'.
•	05 December 2002	Change of manufacturer of the active substance.
•	08 August 2000	Change of MAH.
•	15 May 2000	Change to therapeutic indications.
•	31 March 2000	Change of product name from 'Sorguard Pour-on' to 'Renegade Sheep Pour-on'.