



Post Authorisation Assessments

Premadex 0.5% w/v Pour-on Solution Vm 11990/4039

• 20 March 2023	Change of distributor address from Downland Marketing Ltd. 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
• 04 April 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 01 May 2018	Change in the invented name of the veterinary medicinal product from Sumex 0.5% w/v Pour-on Solution to Premadex 0.5% w/v Pour-on Solution.
• 15 March 2018	Change in distributor details from Chanelle Animal Health Limited, 7 Rodney Street, Liverpool, L1 9HZ to Downland Marketing Ltd, 15 Victoria Place, Carlisle, Cumbria, CA1 1EW, UK.
• 14 November 2016	Submission of an updated certificate of suitability.
• 21 December 2015	Submission of a new certificate of suitability.
• 14 May 2015	Submission of an updated certificate of suitability.
• 04 December 2013	Deletion of a manufacturer responsible for assembly.
• 13 September 2011	To seek approval of mock ups for 2.5 L and 5 L pack sizes
• 13 April 2011	Submission of a new or updated Ph. Eur. certificate of suitability.
• 17 December 2010	Renewal Marketing Authorisation. UK CMS.
• 11 June 2010	Change to in process tests or limits applied during manufacturer of the finished product.
• 04 August 2009	Change in batch size of finished product