Veterinary Medicines Directorate

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Post Authorisation Assessments

Premadex 0.5% w/v Pour-on Solution

Vm 08749/3044

26 September 2025	Change in legal entity of MA holder from Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9EF, United Kingdom to Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co Galway, H62 FH90, Ireland.
12 January 2025	Minor change to an approved test procedure for the finished product. (NI)
11 December 2024	Minor change to an approved test procedure for the finished product. (GB)
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