



Post Authorisation Assessments

Flydown 10mg/ml Spot-on Solution for Cattle and Sheep

•	05 November 2020	Change in distributor details from Downland Marketing Limited, 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
•	01 September 2020	Change in storage conditions of the finished product.
•	19 August 2020	Changes to the labelling and package leaflet.
•	22 May 2020	Change in immediate packaging of the active substance.
•	16 September 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	23 August 2019	Renewal – UK as CMS
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 November 2018	Change in RMS from UK to IE.
•	13 September 2018	Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	13 June 2017	Addition of a secondary packaging site of the finished product.
•	27 October 2015	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.