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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

Hydrocortisone Aceponate Ecuphar 0.584 mg/ml Cutaneous Spray Solution for Dogs

Vm 32742/5000

•	21 November 2023	Unlimited renewal
•	04 January 2023	Change in the address of the local representative from Animalcare Ltd, 10 Great North Way, York, YO26 6RB to Animalcare Ltd, Moorside, Monks Cross, York, YO32 9LB, United Kingdom.
•	01 March 2022	Minor changes to an approved test procedure of the finished product. Replacement of a site where batch control/testing takes place. Replacement of a manufacturing site of the finished product. Replacement of a manufacturer responsible for batch release including batch control/testing. Replacement of a primary packaging site of the finished product. Replacement of a secondary packaging site of the finished product.
•	14 October 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	29 July 2021	Change in the invented name of the veterinary medicinal product from Cortacare 0.584 mg/ml Cutaneous Spray Solution for Dogs to Hydrocortisone Aceponate Ecuphar 0.584 mg/ml Cutaneous Spray Solution for Dogs.