



Post Authorisation Assessments

Adaxio Shampoo for Dogs

•	20 April 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 August 2019	Renewal – UK as CMS
•	13 December 2018	Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Replacement of a manufacturer responsible for batch release of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	01 June 2018	Change in RMS from UK to FR.
•	29 November 2017	BE and LU: Change in the invented name of the veterinary medicinal product from Adaxio Shampoo for dogs to Adaxio 20 mg/ml + 20 mg/ml Shampoo for dogs. DK and NO: Change in the invented name of the veterinary medicinal product from Adaxio 20 mg/ml + 20 mg/ml Shampoo for dogs to Adaxio vet 20 mg/ml + 20 mg/ml Shampoo for dogs.
•	23 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 September 2017	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.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	01 March 2017	Change in the shelf-life of the finished product from 21 months to 24 months.
•	05 January 2017	Submission of an updated Ph. Eur certificate of suitability for an active substance from an already approved manufacturer.
•	16 December 2016	Change in name of the site of batch release of the finished product.
•	06 September 2016	Change in the name and address of the MAH in Italy only.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.

•	24 May 2016	A Change in the specification parameters.
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