Veterinary Medicines Directorate

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Post Authorisation Assessments

Adaxio Shampoo for Dogs

Vm 14966/3043

01 May 2026	Change in the pharmacovigilance system master file (PSMF) location. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
16 October 2025	Change in legal entity of MA holder from Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom to Ceva Sante Animale, 8 rue de Logrono, 33500 Libourne, France.
22 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
13 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
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 an 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.