



Post Authorisation Assessments

Aurimic Ear Drops and Cutaneous Suspension for Dogs and Cats Vm 57446/4004

•	08 August 2023	Change of distributor address from Animalcare Ltd, 10 Great North Way, York, YO26 6RB, United Kingdom to Animalcare Ltd, Moorside, Monks Cross, York, YO32 9LB, United Kingdom.
•	02 June 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	23 January 2023	Change in MAH from Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria to VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria.
•	18 January 2023	Change in shape or dimensions of the container of the finished product.
•	18 January 2023	Change in shape or dimensions of the container for the finished product.
•	16 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	16 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	28 November 2022	Updated certificate of suitability from an already approved manufacture.
•	02 November 2022	Updated certificate of suitability from an already approved manufacturer.
•	31 October 2022	Change in shape of bottle screw cap for the finished product.
•	24 October 2022	Change in shape of bottle for the finished product.
•	22 July 2021	Updates to Quality section of the product dossier.
•	12 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 December 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 November 2019	Renewal – UK as CMS
•	03 October 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 December 2017	Repeat Use application to add 1 new member state
•	19 July 2017	Submission of an updated Ph. Eur. certificate of

		suitability for an active substance manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	June 2016	Local representative to be introduced (Animalcare Ltd) in Ireland and the UK. Mock ups approved.
•	11 May 2016	Submission of an updated certificate of suitability. Addition of a new batch size.
•	10 July 2015	Change in the shelf-life of the finished product, from 21 months to 2 years.