Veterinary Medicines Directorate

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Post Authorisation Assessments

Otomax Ear Drops Suspension

Vm 01708/4588

•	13 January 2021	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	12 December 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 March 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 February 2017	Submission of a new certificate of suitability.
•	06 February 2015	Change to the storage conditions of an active substance. Addition of a new specification parameter for an active substance.
•	18 July 2014	Change to the address of an active-substance manufacturer.
•	28 March 2012	Change in MAH from Schering Plough Ltd to Intervet UK Ltd.
•	28 March 2012	Change in distributor.
•	24 November 2011	Submission of an updated certificate of suitability for an already approved active substance manufacturer.
•	24 November 2011	Deletion of an active substance manufacturing site.
•	28 October 2011	Minor change to the name of an excipient.
•	27 May 2011	Change in the name of a manufacturer of the active substance.
•	14 March 2011	Change of name of MAH in Portugal only.
•	16 July 2010	Change in the manufacturing process of the active substance.
•	16 March 2010	Change in dimensions of immediate packaging.
•	04 February 2010	Renewal.
•	19 June 2009	Changes in test procedures of the finished product.
•	28 June 2006	Renewal.
•	29 July 2005	Addition of a site for micronization.
•	13 July 2005	Addition of a manufacturer of the active substance.
•	23 February 2005	Addition of a manufacturer of the finished product.
•	12 March 2004	Deletion of a manufacturer of the active substance.
•	16 October 2003	Increase in batch size of the active substance.