Veterinary Medicines Directorate

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Post Authorisation Assessments

Otomax Ear Drops Suspension

Vm 01708/4588

07 April 2025	Changes to the labelling or the package leaflet which shall not be connected with the SPC. Changes to the labelling or the package leaflet which shall not be connected with the SPC. Minor editorial amendment to Contraindications section in the package leaflet. Addition of statement regarding determining bodyweight to ensure correct dosage Changes to the labelling or the package leaflet which shall not be connected with the SPC:– other changes. No changes for PhV sections.
07 April 2025	Corrections of minor errors found in the product literature.
20 February 2025	Alignment of product information with version 9.0* of the QRD template.
11 February 2025	Deletion of a manufacturing site for a finished product. Deletion of a manufacturing site for an active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB + NI).
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.