



Post Authorisation Assessments

Otodex Veterinary Ear Drops Solution for Dogs and Cats

Vm 13240/4001

•	11 August 2023	Addition of a primary packaging site of the finished product.
•	11 August 2023	Addition of a manufacturer responsible for batch release.
•	11 August 2023	Addition of a secondary packaging site of a finished product.
•	11 August 2023	Addition of a new site of manufacturing of the finished product.
•	23 May 2023	Deletion of an API supplier.
•	10 March 2023	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	01 September 2022	Deletion of a non-significant specification parameter of the finished product.
•	03 August 2022	Change in name of a manufacturer of the finished product. Addition of a site for quality testing of the finished product.
•	31 July 2019	Changes to the labelling and package leaflet.
•	26 October 2016	Change to manufacturer responsible for batch release.
•	26 October 2016	Change in the manufacturer of the active substance.
•	30 November 2011	Change in manufacturer of the finished product.
•	05 October 2011	Change in site of primary packaging and labelling.
•	19 September 2011	Change in site of batch release.
•	09 December 2009	Replacement of a site of manufacture of the finished product.
•	21 August 2008	Change in address of the MAH.
•	15 July 2008	Replacement of a site of manufacture of the finished product.
•	04 July 2008	Change in site of batch release and batch control/testing.
•	03 July 2008	Changes to the SPC and product literature to bring in line with new legislation.
•	03 July 2008	Change in legal category from GSL to AVM-GSL.
•	23 October 2006	Change in the finished product specifications.
•	12 October 2005	Change in the name of the active substance manufacturer.
•	25 July 2005	Change in the name of the manufacturer of the finished product.
•	07 December 2001	Renewal