



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Neptra Ear Drops Solution for Dogs

Vm 04895/5007

•	15 August 2023	Change in the name and address of the Marketing Authorisation Holder from Bayer Animal Health GmbH 51368 Leverkusen, Germany to Elanco Animal Health GmbH, Alfred-Nobel-Str. 50, 40789 Monheim, Germany.
•	23 November 2022	Approval of mock ups.
•	26 October 2022	Change(s) in the SPC, labelling or package leaflet, to sections 4.6 and 6.
•	21 October 2021	Amendments to the Summary of Product Characteristics and product literature as a result of a review of the cited adverse reactions.
•	30 June 2021	Change in the address of the marketing authorisation holder from Bayer Animal, Health GmbH, Kaiser-Wilhelm-Allee 10, 51373 Leverkusen Germany to Bayer Animal Health GmbH, Kaiser-Wilhelm-Allee 20, Kaiser-Wilhelm-Allee 20, Germany.
•	09 March 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	09 March 2021	Change in shape or dimensions of the container or closure (immediate packaging)
•	26 February 2021	Change in shape or dimensions of the container or closure (immediate packaging)