



## Post Authorisation Assessments

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

### Neptra Ear Drops Solution for Dogs

Vm 04895/5007

•	03 April 2024	Change wording 4.5 following Pharmacovigilance procedure. Post-marketing surveillance shows that the use of the product in cats can be associated with neurological signs, internal ear disorders and systemic sign. The use of the veterinary medicinal product in cats should therefore be avoided.
•	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)